End of Project Report – Enhancing Local Manufacturing and Supply Chain Management for Malaria Commodities.

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Project Summary

Indicators	Target	Progress	Notes
Stakeholder Engagement			
Number of MOUs/institutional agreements signed.	TBD	13	Institutional agreements finalized with 13 organizations.
Number of validation and co-development workshop held.	6[1]	8	A total of six workshops (one in each geo-political zone) were conducted to validate the findings from the national assessment of existing sub-national procurement mechanisms. The workshops were held in the following regions and states: ▪ North East – Gombe State: 15 – 16 September 2025 (15 participants) ▪ North Central – Abuja (FCT): 18 – 19 September 2025 (17 participants) ▪ North West – Kano State: 22 – 23 September 2025 (17 participants) ▪ South West – Lagos State: 25 – 26 September 2025 (15 participants) ▪ South South – Akwa Ibom: 29 – 30 September 2025 (15 participants) ▪ South East - Enugu State: 2 – 3 October 2025 (13 participants) A workshop was held with PMG-MAN in Lagos State from 11–12 September 2025 to assess their current capacity, identify gaps, and determine priority needs. The session was attended by 20 participants. A national stakeholder workshop was held in Abuja from 8–10 October 2025 to validate the findings of all the assessments conducted and to co-create a strategic roadmap for improvement. The workshop brought together 122 participants.
Workforce Capacity for Manufacturing Industry			
Establishment of a web-based training platform to address identified gaps in the industry	Completed	Completed	The Program developed the "Web-based Training Centre" called the **Empower Digital Academy**, which was identified as a top priority by relevant stakeholders in the pharmaceutical industry. The Learning Management System (LMS) will serve as the central hub for training content delivery, progress tracking, and certification.
Number of professionals enrolled on the web-based training platform.	TBD	2,061	Empower Digital Academy with 40 courses, and **2,061 learners** have registered on the platform **(as of Feb 28, 2026)**
Number of processes for product registration identified for targeted support	TBD	4 key gaps identified	Four key gaps in the product registration process were identified through workshops and bilateral engagement with PMG-MAN members between June and September 2025, informing the areas targeted for platform and technical support.

[1] Co-development workshop for RDTs, LLINs, ACTs, regulatory agencies, and pooled procurement.

Indicators	Target	Progress	Notes
Development of a Document Compliance Engine (DCE) platform	Completed	Completed	The project successfully developed a Document Compliance Engine (DCE) platform, an end-to-end compliance workspace that enables seamless preparation, validation, and management of regulatory documentation for healthcare and life sciences.
Number of product registration support processes successfully completed	TBD	10 dossiers	Product registration support was successfully completed for **10 product dossiers** on the DCE platform during the limited pilot conducted with 3 pharmaceutical companies (Evans Baroque, Remedial Health, and Laboratoires Hoefman).
Capacity Building for Manufacturers			
Number of local manufacturers assessed for second-generation malaria RDTs.	7	7	The assessment report was validated during the national stakeholder workshop and subsequently debriefed to the manufacturers on Tuesday, March 3, 2026.
Number of local RDT manufacturers with specific capacity development plans.	4	4	The capacity development plans have been finalized for all manufacturers.
Number of local manufacturers assessed for readiness to produce LLINs.	7	5	The assessment report was validated during the national stakeholder workshop and subsequently debriefed to the manufacturers on Monday, December 1, 2025.
Number of local manufacturers of LLINs with specific capacity development plans	4	3	The capacity development plans have been finalized for all manufacturers.
Number of international technical partnerships established for local manufacturers of LLINs.	2	1	There is a current partnership agreement with Vestergaard.
Number of local manufacturers assessed for readiness to produce ACTs.	7	17	The assessment report was validated during the national stakeholder workshop and subsequently debriefed to the manufacturers on Tuesday, March 3, 2026.
Number of local manufacturers of ACT with specific capacity development plans	4	17	The capacity development plans have been finalized for all manufacturers.
Number of local manufacturers of APIs with specific capacity development plans.	4	2	The assessment identified only two manufacturers across the country that both possess the technical capacity and expressed interest in participating in the production of malaria rapid diagnostic tests. The manufacturers include Emzor Pharmaceuticals and Fidson Healthcare Plc. The capacity development plans of these manufacturers have been finalized.
Number of international technical partnerships established for local manufacturers of APIs.	2	1	Currently, UNITAID is the primary supporting partner for this initiative, while discussions are ongoing with the European Union and the World Bank to explore additional support.
Capacity for Regulatory Agencies			
Number of regulatory agencies assessed.	5	5	The assessment engaged key regulatory and institutional stakeholders, including NIPRID, SON, PCN, the Nigeria Customs Service, and PMG-MAN.
Number of regulatory agencies identified to receive technical support for improved QA processes.	3	5	The assessment identified NIPRID, SON, PCN, the Nigeria Customs Service, and PMG-MAN as key agencies requiring quality assurance (QA) support.

Indicators	Target	Progress	Notes
Number of States that have established a NAFDAC-led Quality Assurance Task Force.	37 (All States + FCT)	N/A	Feedback from the NAFDAC representative during the workshop indicated that these structures already exist at the state level.
Establishment of Pooled Procurement System			
Number of structures assessed (at national and state levels) assessed.	37 (1/state)	37	The procurement structures of all 36 states in Nigeria were assessed.
Number of procurement structures that received technical support from this project.	37	37	All 36 states received technical support. This support included the development of pooled procurement guidelines that can be adopted and domesticated by each state, the development of a costed workplan for pooled procurement, and the institutionalization of a pooled procurement committee in each state.
Number of structures with documented pooled procurement guidelines.	37	37	The pooled procurement guidelines are currently being finalized.
Number of procurement structures with digital inventory systems deployed.	10	Currently being deployed	On 28 November 2025, Medipool invited the PVAC team to a demonstration of its **Integrated Enterprise Resource Planning (ERP) e-purchasing platform**. During the session, Medipool presented the platform's key features and explained how it could improve efficiency, transparency, and performance in Nigeria's pharmaceutical supply chain. The platform will be fully deployed by the end of March 2026.
Capacity for R&D and Vaccine Production			
Number of collaboration opportunities identified with regional vaccine initiatives.	At least 3		The identified partners include: ▪ The World Health Organization (WHO) and Medicines Patent Pool (MPP) (WHO/MPP) ▪ Innovative Biotech and Afriqvax ▪ IVI ACHIEVE 2.0
Number of clinical trial sites identified and assessed.	12	11	
Number of international research partnerships established.	At least 3	3	The partners include - Purpose Africa, Gates Foundation, and IQVIA
Number of persons trained on mRNA vaccine technology production	80	126	A 5-day in-person training on mRNA technology was held in Abuja from 8–12 December 2025, with **31 participants.** The training was facilitated by the Advanced Biologics for Vaccine Development (ABVD). Additionally, a training session was conducted on the 14th of March, 2026, which recorded a total of **95 participants.**
Publications			
Number of articles published	3	3	The program produced three publications: ▪ Assessing Nigeria's Emerging Capacity for Local Manufacturing of Malaria Commodities - https://doi.org/10.9734/ijtdh/2026/v47i11710

Indicators	Target	Progress	Notes
			▪ Governance for Health Security: Lessons from Nigeria's PVAC in Manufacturing Local Malaria Commodities - https://doi.org/10.9734/jammr/2026/v38i16046 ▪ Market Access as the Missing Link: How Structured and Pooled Procurement Can Unlock Nigeria's Health Manufacturing Potential - https://doi.org/10.9734/jemt/2026/v32i11381
Project Management			
Number of bi-weekly meetings conducted with NMEP team.	12	12	12 meetings conducted.
Number of monthly reports submitted.	7	7	7 monthly reports submitted.
Number of quarterly financial reports submitted.	4	4	The reports are currently being finalized.

1.0 Project Background

Nigeria continues to face a high burden of communicable and non-communicable diseases, with malaria ranking among the leading public health challenges. Despite national and global efforts, the country remains heavily dependent on imported health commodities like vaccines, LLINs, diagnostics, ACTs, APIs, and other essential medical supplies. This dependence exposes the health system to supply chain disruptions, fluctuating prices, long procurement timelines, and quality uncertainties.

In response to these longstanding challenges, the Presidential Initiative for Unlocking the Healthcare Value Chain (PVAC) was launched to accelerate Nigeria's transition toward a stronger, more self-sufficient health commodities sector. The initiative aims to strengthen local manufacturing capacities, reform regulatory systems, optimize procurement pathways, and enhance the overall resilience of Nigeria's health supply chain.

Building on this national agenda, the National Malaria Elimination Programme (NMEP), in partnership with key stakeholders and technical partners, initiated a comprehensive project to develop a strategic roadmap for local production of priority malaria commodities: LLINs, RDTs, ACTs, APIs, and vaccines, alongside strengthening regulatory and procurement systems. The project focuses on identifying barriers, assessing local manufacturing readiness, evaluating regulatory capacity, and co-creating strategic pathways that support long-term domestic production.

Since June 2025, the project has progressed through several foundational phases, including:

- **Selection and onboarding of technical consultants** across five workstreams (LLINs, RDTs, ACTs, APIs, Regulatory, Vaccines & Clinical Research, and Procurement Systems).
- **Signing of MOUs and institutional agreements** with partner agencies to formalize roles and commitments.
- **Comprehensive stakeholder engagement**, including introductory workshops, bi-weekly meetings with NMEP, and consultations with manufacturers, regulators, and industry bodies such as NAIP, PMG-MAN and NAFDAC. Introductory letters were developed and signed by PVAC for this purpose, with the Project Management Team coordinating their delivery.
- **Assessment activities**, including national facility visits, desk reviews, and data gathering across manufacturers and regulatory agencies. Add those deliverables- workplan, stakeholder mapping, etc.
- **Policy dialogues and validation workshops**, bringing together government actors, manufacturers, development partners, and experts to review findings and co-create strategic solutions.
- **Publication:** Articles and briefs for publication, focusing on Nigeria's pharmaceutical industry and regulatory landscape, based on findings from recent project assessments.

2.0 Project Objectives and Rationale

2.1 Project Objectives

The overarching objective of this project is to develop a comprehensive strategic roadmap that strengthens Nigeria's capacity to locally manufacture priority malaria commodities, while addressing systemic gaps in regulation, procurement, and clinical research. Specifically, the project seeks to:

1. **Assess the current manufacturing landscape** for key malaria commodities (LLINs, RDTs, ACTs, APIs, vaccines) to determine existing capacity, market conditions, and feasibility for local production.
2. **Identify regulatory bottlenecks and operational inefficiencies** across NAFDAC, subnational ethics bodies, SON, PCN, and other agencies that influence the approval, oversight, and quality assurance of malaria commodities.
3. **Strengthen procurement systems** by evaluating current public sector practices, identifying gaps in state-level procurement structures, and developing frameworks for pooled procurement and predictable demand generation.
4. **Advance clinical research and product development capacity**, supporting Nigeria to participate more actively in vaccine and drug development, trials, and related innovation ecosystems.
5. **Facilitate collaborative stakeholder engagement** to ensure harmonized recommendations, shared ownership, and alignment with PVAC, NMEP, FMoH, development partners, and industry actors.
6. **Produce a unified, costed strategic roadmap** that outlines short-, medium-, and long-term actions required to establish a sustainable, competitive, and high-quality malaria commodities manufacturing ecosystem.

2.2 Project Rationale

Nigeria, despite being home to more than 100 pharmaceutical manufacturers and significant industrial potential, remains the world's largest malaria-burdened country and one of the biggest importers of malaria commodities. The nation continues to rely heavily on external suppliers for critical products such as Active Pharmaceutical Ingredients (APIs), Artemisinin-based Combination Therapies (ACTs), Rapid Diagnostic Tests (RDTs), Long-Lasting Insecticidal Nets (LLINs), vaccines, and clinical trial materials. This dependence underscores a persistent structural vulnerability within the health system.

Relying on imported commodities exposes Nigeria to multiple risks, including global supply chain disruptions—as witnessed during the COVID-19 pandemic—fluctuating prices driven by foreign exchange instability, prolonged procurement timelines, and the circulation of substandard or falsified health products. These challenges are further compounded by weak domestic value-chain integration, resulting in missed economic opportunities and the loss of potential jobs that could be created through a robust local manufacturing ecosystem.

Addressing these gaps requires a deliberate effort to strengthen Nigeria's local manufacturing capacity while modernizing regulatory and procurement systems. Doing so is critical not only for improved health system resilience and national health security but also for economic diversification, industrial development, and sustainable access to high-quality malaria commodities. The Pandemic Vaccine Access and Capacity (PVAC) initiative offers a national platform and political mandate to drive this transformation, and this project is designed to operationalize that mandate within the malaria commodity ecosystem.

3.0 Project Management & Coordination

3.1 Consultant Selection & Contracting

The project adopted a structured, competitive, and transparent procurement approach to select qualified technical partners for each of the four project workstreams and related cross-cutting components. The selection process began in June 2025 with the development of detailed Terms of Reference (TORs) outlining scope, deliverables, timelines, and required expertise. Calls for proposals were disseminated widely, and all submissions underwent a standardized evaluation process led by PVAC, NMEP, and the Project Management Team (PMT). Proposals were assessed based on technical capacity, past performance, experience in pharmaceutical manufacturing or regulatory systems, and alignment with Nigeria's malaria product ecosystem priorities. Following the evaluation, the following firms were selected:

- **API Manufacturing Capacity Development Technical Assistance:** United States Pharmacopeia (USP).
- **ACT & RDT Capacity Development Technical Assistance:** Clinton Health Access Initiative (CHAI).
- **ACT Assessment:** MedRealm Pharmaceuticals & Consulting Limited.
- **RDT Assessment:** Sages Synergy Integrated Systems.
- **LLIN Capacity Development Technical Assistance:** Access-Centric and Sustainability Foundation (ASF).
- **Vaccine Production and R&D Assessment:** Nigeria Sovereign Investment Laboratory (NSIL).
- **PMG-MAN Institutional Capacity Assessment and E-Learning Platform Development:** Empower SWISS.
- **Other Regulatory Agencies Assessment:** Capacity Connect Limited.
- **Harmonization of Manufacturing Regulatory Standards:** New Vale Nigeria Limited.
- **Harmonization of Clinical Research Regulatory Standards:** Green Fountain Medical Services.
- **Development of a Document Compliance Engine (DCE) Platform:** Infinity Health Africa.
- **Training of Selected Professionals on mRNA Technology for Vaccine Production:** Advanced Biologics and Vaccine Development (ABVD).

Following consultant selection, contracts were finalized in July 2025. These contracts clearly outlined deliverables, timelines, data-sharing requirements, confidentiality obligations, and collaboration expectations with all relevant stakeholders.

Onboarding meetings were conducted for all consultants, led by PVAC with participation from NMEP and the PMT. The onboarding sessions clarified project objectives, reporting structures, alignment with the policy context, communication protocols, and the expected engagement with regulatory and manufacturing stakeholders. These meetings ensured that all workstreams started with a unified understanding of the project's direction and deliverables.

3.2 Governance & Meeting Structure

To ensure smooth coordination across all workstreams, the project deployed a structured governance and meeting structure that enabled continuous communication, oversight, and alignment among consultants, government partners, and the PMT.

Weekly Workstream Meetings:
Each workstream was assigned a dedicated weekly meeting day where consultants met with the PMT to provide progress updates, review preliminary findings, highlight bottlenecks, and receive real-time feedback. These short, targeted check-ins helped maintain timelines, ensured quality control, and allowed the PMT to track deliverables across all components consistently.

Bi-weekly NMEP–PVAC Stakeholder Meetings:
Every two weeks, NMEP, PVAC, and the PMT convened to review cross-workstream progress, harmonize technical inputs, address data and stakeholder engagement challenges, and align emerging findings with national malaria elimination priorities. These sessions strengthened transparency, improved collaboration, and ensured that government counterparts-maintained oversight and ownership of the process.

Monitoring & Evaluation Mechanism:
A structured M&E framework was established at project onset. The PMT produced bi-weekly and monthly tracking reports capturing status updates, achieved milestones, upcoming tasks, risks, and mitigation actions. This mechanism ensured early identification of delays, supported evidence-based decision-making, and enabled the project to remain aligned with the overall timeline leading up to the development of the final roadmap.

4.0 Overview of the Workstreams

The project is organized into four interconnected technical workstreams. Each workstream is led by specialized consultants and focuses on a critical component of the malaria commodity value chain.

4.1 Workstream 1: Local Manufacturing of Malaria Commodities (LLINs, RDTs, ACTs, APIs, Vaccines)

This workstream provided a comprehensive assessment of Nigeria's capacity to locally produce essential malaria commodities by reviewing the entire manufacturing ecosystem. It examined production capacity, supply chain bottlenecks, and the availability of key inputs, while also identifying the technical, financial, and operational constraints that limited Nigeria's ability to meet domestic demand and remain competitive.

The analysis covered plant capacity, technology and machinery readiness, raw material availability, workforce capabilities, and cost structures. It also incorporated feasibility considerations to understand what scale-up would have required across practical, financial, and regulatory dimensions.

The assessment focused on five priority commodity categories—Long-Lasting Insecticide Nets (LLINs), Rapid Diagnostic Tests (RDTs), Artemisinin-based Combination Therapies (ACTs), Active Pharmaceutical Ingredients (APIs), and Vaccines, offering a clear picture of Nigeria's manufacturing strengths, gaps, and growth opportunities.

4.2 Workstream 2: Strengthened Regulatory System and Clinical Research

This workstream examined how regulatory bottlenecks impacted the entire lifecycle of malaria commodity development, from manufacturing and quality assurance to ethical approvals, research governance, and the importation of raw materials. It reviewed key processes led by the National Agency for Food and Drug Administration and Control (NAFDAC), the Standards Organisation of Nigeria (SON), and the Pharmaceutical Council of Nigeria (PCN), as well as ethics committee approvals and adherence to quality standards. The scope also encompassed the research ecosystem, including clinical trials, ethics governance, research infrastructure and biorepositories, and connections between academia, industry, and government. Additionally, the workstream evaluated the governance structure of PMG-MAN, highlighting their current gaps and pathways for improvement.

By mapping these systems, the workstream identified delays, duplications, and capacity gaps that hindered innovation and slowed local production. The aim was to streamline, accelerate, and harmonize regulatory and research functions, thereby improving Nigeria's contribution to global malaria innovation and laying the groundwork for future local production of malaria commodities.

4.3 Workstream 3: Strengthened Procurement Systems & Demand Generation

This workstream concentrated on the purchasing, forecasting, warehousing, and distribution frameworks at both federal and state levels. Activities included assessing state Drug Management Agencies (DMAs), reviewing procurement methods such as framework agreements, tenders, and pooled procurement, analysing demand patterns, strengthening state-level procurement

committees, and enhancing transparency, accountability, and coordination across the supply chain.

By improving these systems, the workstream aimed to create stable and predictable demand signals, which are vital for guiding manufacturers' investment decisions and supporting the growth of local industries production.

5.0 Implemented Activities

5.1 Comprehensive Summary of Assessments Conducted across Workstreams

As part of the PVAC Malaria programme, a series of coordinated assessments were conducted across key thematic workstreams to understand Nigeria's current capacity for local manufacturing, research, regulatory oversight, and pharmaceutical systems strengthening. These assessments provided a baseline of institutional readiness, infrastructure, governance structures, and operational capabilities required to support scaled local production and improved public-health delivery. The process involved extensive fieldwork, multi-stakeholder engagement, document reviews, and structured analysis across several manufacturing, research, and regulatory ecosystems.

RDT Manufacturing Capacity Assessment

An institutional capacity assessment was conducted in seven Nigerian entities identified as prospective manufacturers of malaria rapid test kits. Four companies completed the assessment, after which validation visits were conducted to verify the details submitted during the initial data-gathering stage. These on-site verification visits enabled the team to assess facility readiness, confirm the presence of installed equipment, observe production floors, and evaluate staffing and quality-management systems.

Among the four fully assessed entities, three possessed functional manufacturing facilities at varying levels of operational readiness. Two facilities had advanced to the stage of operating production lines and were awaiting regulatory clearance for full-scale commercial release, while the third was completing equipment installation and commissioning. In addition to physical capacity, the assessment also reviewed organisational compliance structures, including certification status, management systems, and participation in international review bodies. This provided a comprehensive view of the extent to which local producers align with regulatory and quality expectations.

ACT Manufacturing Capacity Assessment

The assessment of local Artemisinin-based Combination Therapy (ACT) manufacturers involved seventeen pharmaceutical companies across eight states: Ogun, Lagos, Enugu, Oyo, Kwara, Imo, Delta, and Ondo. The evaluation was conducted in two phases.

The first involved a structured self-assessment in which companies completed detailed questionnaires covering governance, infrastructure, production capability, market readiness, regulatory compliance, and quality assurance systems. This phase gathered quantitative and qualitative data on organisational structures and technical capacity.

The second phase consisted of on-site verification visits to all seventeen manufacturers. During these inspections, the assessment team physically reviewed production lines, examined equipment and facility layouts, assessed staff competencies, and evaluated documentation and quality-control systems. This mixed-methods approach ensured that reported information was validated and that the assessment accurately captured the operational reality across ACT production facilities.

API Manufacturing Capacity Assessment

The project conducted a national assessment to determine the baseline capacity to produce APIs locally, especially those needed for antimalarial medicines. The assessment engaged manufacturers, policymakers, procurement agencies, and development partners through

multiple data-collection methods. A structured survey was administered to 12 manufacturers and industry associations, as well as five policy and procurement agencies. Four manufacturers responded to the survey, collectively representing about 70% of Nigeria's antimalarial finished pharmaceutical product (FPP) capacity. Additional insights were obtained through consultations with federal institutions, regulatory bodies, and sector stakeholders.

The assessment was further strengthened by a comprehensive desk review of policies, regulatory guidelines, global API production frameworks, and past capacity assessments. A comparative market analysis benchmarked Nigeria's API landscape against regional and international manufacturing ecosystems. Collectively, these processes established a reliable baseline for understanding national capability and areas requiring investment.

LLIN Manufacturing Capacity Assessment

The Long-Lasting Insecticide-Treated Net (LLIN) capacity assessment provided a comprehensive review of Nigeria's preparedness to manufacture LLINs locally. The assessment mapped both upstream and downstream elements of the LLIN value chain. Upstream evaluations involved facility inspections to assess yarn extrusion, weaving or knitting processes, insecticide incorporation technologies, and packaging systems. Downstream components examined included warehousing, distribution structures, last-mile delivery systems, and end-of-life product management.

The assessment also reviewed the regulatory status of manufacturers including CAC registration, NAFDAC and SON certification processes, and readiness for WHO Prequalification. Extensive stakeholder engagement helped capture perspectives from manufacturers, technical partners, raw-material suppliers, and ecosystem actors. This provided a holistic understanding of the institutional and operational structures underpinning LLIN production.

R&D, Vaccines and Clinical Trials Capacity Assessment

The research and clinical trials workstream undertook a wide-ranging national assessment across 21 institutions, covering federal research centres, universities, teaching hospitals, biotechnology companies, and clinical-trial units. The assessment was conducted between June and September 2025 and employed a triangulated methodology.

Structured institutional assessment tools were used to gather data on governance structures, laboratory capacity, human resources, ethics systems, supply chain processes, and financial stability. Key informant interviews were held with institutional leaders, principal investigators, laboratory heads, ethics officials, and technical staff. These interviews provided rich insight into operational realities, institutional challenges, and research-management systems.

Physical site visits were carried out at six institutions: CAMRET-UDUS, BioRTC Yobe, NARICT Zaria, CIDR-BUK, Biovaccine Nigeria Ltd., and Innovative Biotech. These visits helped the team directly observe laboratory conditions, assess equipment status, review documentation, and verify internal processes.

Regulatory Landscape Assessment

Assessment of Regulatory Agencies:

The assessment used a mixed-methods approach. Desk reviews were used to analyze existing policies, regulatory guidelines, operational documents, and previous assessments related to the mandates and performance of key regulatory bodies such as NAFDAC, PCN, SON, and NIPRD. This was complemented by structured reviews of national frameworks governing the production and quality assurance of malaria commodities, helping to identify policy gaps, overlaps, and areas requiring harmonization. Together, the desk reviews and key informant interviews offered a

comprehensive understanding of how the regulatory ecosystem functions and where reforms are most needed.

Assessment of PMG-MAN:
The project assessed PMG-MAN's capacity to strengthen industrywide compliance through digital training and enhanced self-regulation. The assessment explored governance structures, coordination mechanisms, voluntary compliance audits, internal communication systems, and industry engagement platforms.

The evaluation reviewed documentation from PMG-MAN's internal systems, compliance checklists, and workforce-training records. Discussions with association leadership and manufacturing representatives helped establish capacity gaps, training needs, and readiness for digital learning adoption. The assessment also examined ICT infrastructure within facilities as a determinant of digital readiness.

Document Compliance Engine (DCE) Assessment:
The DCE workstream conducted a structured review of the documentation landscape within Nigerian pharmaceutical manufacturing. The assessment aimed to identify gaps that contribute to inconsistent regulatory submissions and prolonged approval timelines.

The process involved three phases: mapping industrywide documentation challenges, consulting PMG-MAN members on dossier preparation practices, and assessing digital readiness and internal quality-assurance frameworks. These steps clarified the requirements for an automated compliance platform capable of supporting standardised regulatory submissions.

DMA/DPS Capacity Assessment
A comprehensive nationwide assessment was conducted to evaluate the operational readiness and functional capacity of state-level Drug Management Agencies (DMAs) and Departments of Pharmaceutical Services (DPS). The assessment examined multiple dimensions, including governance structures, financing mechanisms and Drug Revolving Fund (DRF) systems, warehousing infrastructure, supply-chain management processes, quality assurance protocols, human resource capacity, and the extent of partner engagement and coordination.

Data collection was carried out through a combination of approaches, including in-depth consultations across all 36 states and the Federal Capital Territory (FCT), systematic reviews of relevant state policies, strategic and operational documents, and structured assessment tools designed to identify capacity gaps and operational bottlenecks. The assessment also included field engagement with state teams, supply-chain officers, development partners, and technical units to ensure a holistic understanding of operational realities, challenges, and opportunities to strengthen state pharmaceutical systems.

5.2 Stakeholder Workshops

PVAC–PMG-MAN Capacity Strengthening Workshop
The two-day consultative workshop was convened by PVAC, PMG-MAN, InSight Health Consulting, Empower Swiss, and Infinity Health to jointly assess PMG-MAN's technical and digital capacity needs and co-develop actionable plans for strengthening regulatory, operational, and workforce readiness across Nigeria's pharmaceutical manufacturing sector.

The meeting brought together 20 participants representing government, industry, technical partners, and facilitators and was held between 11–12 September 2025. The workshop aimed to (i) review PMG-MAN's institutional and technical capacity gaps; (ii) jointly develop short- and medium-term capacity-building plans; (iii) assess existing digital systems and identify

opportunities for automation; (iv) review prototype digital tools; and (v) agree on implementation steps for strengthening the association's technical and digital ecosystem.

The workshop brought together members of PMG-MAN to strengthen Nigeria's pharmaceutical manufacturing ecosystem and enhance both operational and digital capacity. Discussions highlighted the current landscape, emphasizing opportunities for expanding local production alongside persistent regulatory and capacity challenges affecting member companies. Participants engaged in group activities to assess key aspects of technical capacity, including regulatory readiness, workforce skills, infrastructure constraints, and training needs, while also evaluating digital maturity, system gaps, and opportunities for automation, data sharing, and improved regulatory communication.

The groups' analyses provided a detailed understanding of gaps across financing, data management, regulatory processes, supply-chain systems, human resource capacity, innovation adoption, and market access. In parallel, a phased roadmap for digital enhancements was developed, covering module development, data-privacy controls, system validation, ICT training, pilot deployment, and scale-up strategies.

The workshop concluded with a comprehensive action plan that combined technical capacity building and digital transformation. Key priorities included structured training programmes, targeted resource mobilisation, and pilot testing of digital tools in selected facilities. The workshop's outcomes outlined a clear, actionable pathway towards a more resilient, efficient, and digitally enabled pharmaceutical manufacturing network capable of supporting national self-sufficiency and improved regulatory compliance.

Regional Validation Workshops for Sub-National Procurement System Assessments

The Procurement Systems Strengthening Workshops brought together state-level procurement stakeholders from each of Nigeria's six geopolitical regions to review assessment findings and collaboratively design practical solutions for improving malaria commodity procurement. Each regional workshop convened representatives from Drug Management Agencies (DMAs), Departments of Pharmaceutical Services (DPS), State Ministries of Health, and NMEP, ensuring comprehensive representation and inclusive regional dialogue.

During the workshops, participants reviewed validated findings from earlier sub-national procurement assessments, which highlighted disparities in procurement structures, weak governance systems, inconsistent committee functionality, gaps in forecasting and supply planning, and challenges in warehousing, documentation, and ICT readiness. States confirmed the accuracy of the results and contributed additional context on state-specific procurement barriers.

Breakout sessions within each region enabled states to refine and enrich the findings and develop tailored, state-specific procurement capacity-strengthening plans. These plans outlined actions, reforms, training needs, and system improvements required to strengthen procurement operations and align with PVAC's goals. The workshops also addressed the functionality of existing state-level procurement committees. While most states had such committees, many were inactive or lacked clearly defined roles. Participants emphasized revitalizing committees, establishing new pooled procurement committees where needed, standardizing composition, including malaria-specific expertise, and strengthening TORs and oversight mechanisms.

By the end of the regional workshops, participants reached consensus on key next steps, including finalizing state capacity plans, identifying states requiring new or strengthened procurement committees, and developing a national procurement improvement framework to feed into the PVAC Strategic Roadmap. The workshops provided a platform for states within each region to validate findings, co-create solutions, and align on procurement reforms, laying the foundation

for targeted technical assistance, stronger governance, and improved access to quality malaria commodities across Nigeria.

National Validation and Co-Creation Workshop

A three-day national workshop brought together more than 116 stakeholders from government, regulatory agencies, industry, academia, and development partners. The aim was to validate findings from the eight technical assessments conducted across manufacturing, regulatory, research, and supply chain workstreams, and to develop a coordinated roadmap to strengthen Nigeria's capacity for local malaria commodity production and distribution.

The workshop convened stakeholders across Nigeria's pharmaceutical manufacturing and research sectors to assess the country's capacity to produce essential health commodities and develop actionable strategies to strengthen local systems. Discussions highlighted Nigeria's growing yet constrained manufacturing base, heavy reliance on imported raw materials, regulatory bottlenecks, limited automation, and underdeveloped quality systems. Presentations on APIs, ACTs, LLINs, RDTs, and vaccine and clinical research capacity underscored these challenges. At the same time, the Digital Training and Self-Regulation component emphasized the need for standardized, industry-wide training. The Document Compliance Engine (DCE) was showcased as a digital tool to improve regulatory dossier preparation and reduce submission errors. Participants stressed the importance of affordable financing, harmonized regulations, and incentives to expand domestic capacity.

Attention then turned to regulatory and supply chain systems, revealing overlapping agency mandates, limited laboratory capacity, weak digital systems, and inconsistent clinical research oversight. The procurement and supply chain assessment highlighted fragmented state-level procurement structures, insufficient warehousing standards, limited LMIS digitization, and heavy dependence on donor support. Participants worked in three technical groups—Manufacturing, Regulatory/Clinical Research, and Procurement & Supply Chain—to translate findings into strategic roadmaps. Each group analyzed critical constraints, identified decision-makers and influencers, proposed technical interventions, defined realistic timelines, and documented risks with mitigation strategies.

In synthesizing outputs, the Manufacturing group prioritized investment, multi-year demand guarantees, access to capital, and the establishment of shared R&D and pilot-scale facilities. The Regulatory/Clinical Research group highlighted the need to resolve regulatory duplication, modernize compliance systems, digitalize submissions, and strengthen ethics oversight. The Procurement & Supply Chain group focused on activating state-level procurement capacity, digitizing LMIS, improving warehousing standards, and reinforcing DRF structures to support predictable demand for locally manufactured products. The workshop concluded with a shared commitment from PVAC, NMEP, and partners to implement the harmonized roadmap, advance local manufacturing, enhance regulatory coordination, and build a resilient supply chain capable of supporting Nigeria's malaria elimination goals.

5.3 Project Technical Support

Assessment Debrief with Manufacturers

The consultants who carried out the assessment of manufacturers producing Artemisinin-based Combination Therapies (ACTs), Long-Lasting Insecticide Nets (LLINs), Active Pharmaceutical Ingredients (APIs), and Rapid Diagnostic Tests (RDTs) held a comprehensive debriefing to present the detailed findings of their evaluation. Their assessment covered a broad range of aspects across the manufacturing ecosystem, including production capacity, quality management systems, regulatory compliance, workforce skills, supply chain management, and research and development capabilities. The debriefing provided stakeholders with an in-depth understanding

of the strengths, weaknesses, opportunities, and gaps in each manufacturer's operations, highlighting areas requiring improvement to enhance efficiency, ensure product quality, and increase self-sufficiency in local production of essential malaria commodities.

In addition to presenting their findings, the consultants outlined specific capacity development plans tailored to the unique needs of each manufacturer. These plans aimed to address identified gaps and build on existing strengths, ensuring that interventions were both practical and targeted. Key elements of the capacity development plans included workforce training programmes focused on technical skills, quality assurance, and regulatory compliance; upgrades to manufacturing processes and infrastructure to meet international standards; strengthening of research and development capabilities to foster innovation; and enhancement of supply chain and procurement systems to ensure timely access to raw materials and finished products. The plans also highlighted the importance of aligning manufacturers' operations with national regulatory frameworks and international best practices to improve market competitiveness and sustainability.

The debriefing session served as a critical platform for dialogue between the consultants, manufacturers, government representatives, and other stakeholders. It facilitated a shared understanding of the current state of the local manufacturing ecosystem and set the stage for collaborative implementation of the capacity-building initiatives. By providing detailed, actionable recommendations and practical development pathways, the consultants ensured that the manufacturers were equipped not only to enhance production efficiency and quality but also to contribute more effectively to Nigeria's broader health security goals and reduce dependence on imported malaria commodities. This approach underscored the strategic importance of a coordinated, data-driven, and capacity-focused intervention for strengthening the local malaria commodity manufacturing sector.

Development of a Document Compliance Engine (DCE)

The Document Compliance Engine (DCE) is an innovative digital platform developed by Infinity Health Africa in partnership with the Pharma Manufacturers Group of the Manufacturers Association of Nigeria (PMG-MAN) and PVAC. The DCE currently serves as a secure, intelligent, and digital-first compliance infrastructure, actively helping Nigerian manufacturers prepare, validate, and manage regulator-ready dossiers with clarity and speed. The platform's primary objective is to solve the endemic problems of **disconnected processes, incomplete submissions, and prolonged approval cycles** that plague the sector, resulting in high rejection rates and prolonging the time it takes for essential medicines to reach the market.

The engine's core services include three key features:

- **Validator:** This tool runs immediate compliance checks on a manufacturer's dossier and submission files, ensuring they meet the regulator's requirements and eliminating errors before the official submission.
- **CTD Builder:** This component aids in structuring and generating all documentation in a regulator-ready format, such as the Common Technical Document (CTD), thereby simplifying the complex task of compiling an accurate dossier.
- **Document Management:** This feature provides a central, secure repository for all regulatory documentation, ensuring documents are properly organized, version-controlled, and easily accessible.

By automating these crucial steps, the DCE will strengthen regulatory readiness for Nigerian manufacturers.

The platform was validated through a pilot study involving five pharmaceutical manufacturers, providing a practical test of its functionality and effectiveness. The study documented specific

compliance gaps within the participating PMG-MAN member companies and demonstrated how the Digital Compliance and Enforcement (DCE) platform successfully addressed these issues through structured workflows, real-time monitoring, and automated tracking. The pilot also generated key metrics on platform performance, governance, and implementation progress, including user engagement, compliance reporting accuracy, and efficiency gains in document management. These results confirmed the platform's ability to streamline compliance processes, reduce administrative burdens, and enhance transparency and accountability. Overall, the pilot demonstrated that the DCE platform can support a digital transition in Nigeria's pharmaceutical regulatory landscape, promoting more efficient, standardized, and traceable compliance practices that strengthen local manufacturing and ensure adherence to national and international standards.

Establishment of a Web-based Training Centre

Following a comprehensive situational analysis and a detailed training needs assessment, a structured plan for curriculum design, delivery, and quality assurance was developed, leading to the establishment of the **Web-based Training Centre**. Identified as a top priority by the Pharmaceutical Manufacturers Group of the Manufacturers Association of Nigeria (PMG-MAN) and the broader pharmaceutical industry, this learning management system (LMS) serves as the central platform for delivering training content, tracking learner progress, and issuing certifications, laying the foundation for scalable, traceable, and standardized capacity-building across the sector.

The LMS is designed to be intuitive and fully functional, offering learner dashboards to monitor progress, digital certificates to recognize achievements, and mobile access to ensure flexibility and convenience. On the administrative side, the platform includes course hosting, user management, progress tracking, assessments, digital badges and certificates, reporting dashboards, SCORM-compliant modules, and mobile-friendly interfaces. These features collectively ensure that training delivery is efficient, measurable, transparent, and aligned with industry standards.

The curriculum covers essential areas for strengthening the pharmaceutical sector, including pharmaceutical management, pharmaceutical manufacturing, regulatory compliance, Good x Practice (GxP), validation processes, and supply chain management. By providing this comprehensive training, the Web-based Training Centre equips industry professionals with the knowledge and skills needed to improve operational efficiency, regulatory compliance, and overall performance, ultimately supporting the growth and sustainability of local pharmaceutical manufacturing in Nigeria.

Implementation of the mRNA Training Program

In a strategic effort to strengthen Nigeria's capacity for local vaccine production, the project launched an open call for applications to the mRNA Technology Training Program, targeting professionals in relevant fields such as parasitology, immunology, veterinary medicine, microbiology, and related disciplines. Selection was based on a transparent, pre-agreed set of criteria, including years of professional experience and demonstrated expertise in relevant areas. Following this process, a total of 31 highly qualified participants were selected from across the six geo-political zones of the country, ensuring a diverse and representative cohort.

The program was structured as an intensive five-day training designed to provide participants with both theoretical knowledge and hands-on practical experience in mRNA technology. Key areas covered included mRNA design, synthesis, formulation, delivery systems, and quality control, equipping participants with a deep understanding of the science and technical processes underpinning modern vaccine development. In addition to classroom-based instruction, the training featured hands-on laboratory sessions and collaborative learning exercises, allowing

participants to apply concepts in practical settings and gain skills directly relevant to local vaccine and biologics manufacturing.

The training was facilitated by the **Advanced Biologics and Vaccine Development (ABVD)**, a nonprofit organization committed to transforming vaccine manufacturing and advancing the biologics industry through high-impact capacity-building initiatives. By providing participants with specialized technical knowledge, practical laboratory experience, and opportunities for peer learning, the program significantly enhanced the capacity of Nigerian professionals to contribute to the country's growing biotechnology and vaccine development ecosystem. This initiative represents a critical step toward building a skilled workforce capable of supporting sustainable local vaccine production and strengthening national health security.

6.0 Key Achievements

6.1 Cross-Cutting Key Achievements

Across all workstreams, the assessments revealed a maturing and increasingly coordinated ecosystem for the local manufacturing of malaria health commodities. Taken together, these achievements demonstrate significant progress in Nigeria's industrial readiness, regulatory alignment, digital transformation, and institutional coordination.

Strengthened Local Manufacturing Capacity Across Commodities

Assessments across all workstreams highlighted a maturing and increasingly coordinated ecosystem for the local production of malaria health commodities. Manufacturers of Artemisinin-based Combination Therapies (ACTs), Rapid Diagnostic Tests (RDTs), Long-Lasting Insecticidal Nets (LLINs), and Active Pharmaceutical Ingredients (APIs) demonstrated significant and growing domestic capacity. ACT manufacturers collectively possess installed capacity exceeding national demand, with several achieving Good Manufacturing Practice (GMP) certification and maintaining robust quality systems. RDT manufacturers have made substantial progress in regulatory alignment, with multiple firms achieving ISO 13485:2016 certification, Enterprise Resource Planning Development (ERPD) recognition, and readiness for World Health Organization Prequalification (WHO PQ). LLIN manufacturers completed key infrastructure upgrades—including weaving and coating equipment—and strengthened quality-management processes in preparation for WHO PQ requirements. API-related assessments highlighted foundational capacity and demonstrated strong industry interest in transitioning toward upstream ingredient production. Collectively, these achievements represent major steps toward reducing Nigeria's dependence on imports for essential malaria commodities.

Improved Regulatory Compliance and Governance Structures

The assessments also revealed significant improvements in regulatory readiness, driven by agencies including the National Agency for Food and Drug Administration and Control (NAFDAC), the Standards Organisation of Nigeria (SON), the Pharmaceutical Council of Nigeria (PCN), the Medical Laboratory Science Council of Nigeria (MLSCN), and the National Health Research Ethics Committee (NHREC). Manufacturers increasingly adopted formal quality management systems aligned with global standards, while regulatory oversight benefited from clearer oversight structures and greater interagency engagement. Coordination among ethics committees, NAFDAC, and NHREC in clinical research assessments further reflected emerging efficiencies. These advancements provide a stronger foundation for WHO PQ pathway readiness and international certification.

Digital Transformation Gains: Industry Self-Regulation and Learning Systems

The assessments marked significant progress in digital capability-building within Nigeria's pharmaceutical manufacturing sector. The industry has established a voluntary self-regulation system within PMG-MAN, complete with regular audits. Digital learning infrastructure needs were identified to support competency-based training across regulatory, quality, and production domains. Strong governance practices within PMG-MAN were recognized as capable of supporting structured digital transformation. These developments reflect growing momentum toward embedding continuous improvement and compliance within manufacturing systems.

Progress Toward Digital Compliance and Standardized Regulatory Submissions

The Digital Compliance Engine (DCE) assessment highlighted a major breakthrough in addressing longstanding documentation and dossier challenges. Manufacturers and regulators collaboratively identified key compliance barriers, leading to the conceptualization of a structured digital platform to standardize dossier preparation, reduce errors, and improve approval timelines. PMG-MAN validated the platform's importance and expressed readiness for

phased piloting, representing one of the most transformative achievements in the regulatory environment for local manufacturers.

Improved National Coordination and Policy Momentum

The assessments also reflected unprecedented alignment among government, private sector, and development partners on promoting local manufacturing, digital regulatory reform, supply-chain strengthening, financing reforms, and demand-shaping policies. Multi-agency collaboration involving the Federal Ministry of Health (FMoH), Federal Ministry of Trade, Industry, and Investment (FMITI), Nigeria Sovereign Investment Authority (NSIA), Bank of Industry (BOI), NAFDAC, NMEP, PVAC, and PMG-MAN has laid the foundation for a harmonized national roadmap.

6.2 Cross-Cutting Challenges

Despite significant achievements, the assessments reveal persistent system-level constraints that affect all workstreams.

Demand Uncertainty and Limited Market Guarantees

A significant constraint across ACTs, RDTs, LLINs, and APIs is the absence of predictable, multi-year procurement. Current donor procurement rules, particularly the requirement for World Health Organization Prequalification (WHO PQ), continue to suppress domestic uptake and discourage long-term investment. Without guaranteed demand, manufacturers are unable to scale production, plan for capacity expansions, or commit to costly technological upgrades. This uncertainty not only limits industrial growth but also undermines the stability of the domestic supply chain for essential malaria commodities.

Limited Access to Affordable, Long-Tenure Financing

Manufacturers consistently reported challenges in securing financing for growth and upgrades. High interest rates, foreign exchange scarcity, short loan tenures, and delays in accessing government incentives restrict the ability to invest in technology upgrades, procure raw materials, and align products with WHO PQ standards. These financial constraints remain a key barrier to scaling local production and affect manufacturers' capacity to respond rapidly to changing demand or supply chain disruptions.

Heavy Dependence on Imported Inputs

The sector remains highly dependent on imported inputs, including APIs and excipients, LLIN yarns, polymers, insecticides, RDT antibodies, nitrocellulose membranes, and buffers. This reliance increases production costs and exposes manufacturers to global supply chain shocks, currency volatility, and logistical delays, reducing competitiveness and limiting the potential for local value addition.

Gaps in Testing, Accreditation, and Certification Infrastructure

Critical laboratory and testing infrastructure deficiencies were identified across all manufacturing sectors. These include the absence of WHO-compliant entomology laboratories, lack of accredited diagnostic reference labs, limited bioequivalence centres, and inadequate insecticide-testing facilities. These gaps compel manufacturers to depend on overseas testing, leading to higher costs, extended timelines for product certification, and delayed market entry, which further discourages investment in local manufacturing capacity.

Fragmented Regulatory Systems and Duplication of Requirements

The regulatory landscape remains fragmented, with multiple agencies overseeing overlapping areas of quality and compliance. This results in inconsistent standards, procedural delays, duplication of efforts, and increased compliance costs. While digital solutions have begun to harmonize processes, full integration across agencies has not yet been achieved, limiting efficiency and predictability for manufacturers navigating regulatory requirements.

Workforce Capacity Gaps Across the Value Chain

Manufacturers reported widespread shortages in critical skills, including digital literacy, quality assurance and quality control, regulatory affairs, process chemistry, and industrial engineering. The assessment highlighted the absence of structured digital learning systems and competency-based training, emphasizing the need for targeted workforce development programs to strengthen technical capacity, improve operational efficiency, and sustain compliance with international standards.

Documentation and Dossier Weaknesses

The Digital Compliance Engine (DCE) workstream identified persistent challenges in regulatory documentation and dossier preparation. Common issues included inconsistent formatting, missing documents, weak version control, non-standard templates, and fragmented internal review structures. These deficiencies contribute to delayed regulatory approvals, frequent resubmissions, and increased administrative burden, slowing the pathway to market for locally produced malaria commodities.

Digital Readiness Gaps

The DCE assessment highlighted gaps in digital readiness across manufacturing sites. Limitations included inadequate ICT infrastructure, low staff digital literacy, and reliance on manual systems that hinder traceability, auditability, and overall operational efficiency. Addressing these gaps is critical to enabling digital compliance, data-driven decision-making, and long-term industrial transformation.

6.3 Recommendations

Financing and Incentive Mechanisms

To support sustainable growth in local pharmaceutical manufacturing, it is critical to strengthen financing and incentive structures. This includes establishing a **Health Manufacturing Blended Finance Facility** that provides long-term, single-digit financing, working capital, and grants linked to World Health Organization Prequalification (PQ). Additionally, implementing a preferential foreign exchange window for health manufacturing inputs and accelerating the disbursement and enforcement of existing fiscal incentives will help reduce financial barriers for manufacturers, enabling investment in capacity upgrades, technology, and quality systems.

Market Shaping and Demand Assurance

Predictable demand is essential to stimulate long-term investment. Multi-year framework contracts and demand guarantees across ACTs, LLINs, RDTs, and APIs will provide manufacturers with the confidence to scale production and pursue PQ certification. Donors should adopt tiered procurement pathways, allowing a progressive transition from NAFDAC approval through Enterprise Resource Planning Development (ERPD) to PQ. Strengthening state-level procurement reforms will further improve domestic market absorption and create more reliable demand signals.

Strengthening Digital Transformation and Documentation Systems

Digital systems are critical for improving workforce competency, regulatory efficiency, and compliance. Scaling digital learning for the pharmaceutical workforce requires establishing a National Digital Learning Centre of Excellence, implementing competency-based training across GMP, QA/QC, regulatory affairs, and documentation, and developing industry-wide digital training standards. In parallel, the **Digital Compliance Engine (DCE)** should be implemented nationally to enhance regulatory efficiency. Piloting the DCE in selected PMG-MAN companies, integrating it with NAFDAC's digital systems, standardizing templates and vocabularies, and strengthening

document version control and audit trails will dramatically reduce dossier errors and regulatory delays, improving overall industry compliance.

Regulatory Harmonization and Quality Infrastructure

Creating a **single digital regulatory window** linking NAFDAC, SON, PCN, MLSCN, and NHREC will streamline oversight and reduce duplication. Investments in national entomology laboratories, bioequivalence (BE) centers, and diagnostics reference labs are necessary to support local production and WHO PQ readiness. Structured technical assistance and cost-sharing mechanisms will further facilitate compliance and quality assurance across manufacturers.

Industrial Policy and Local Content Enforcement

Strengthening industrial policy and local content enforcement is vital to incentivize investment. Operationalizing tax exemptions, duty waivers, and depreciation allowances, alongside the establishment of a **Local Manufacturing Implementation Taskforce** to monitor compliance and coordinate agencies, will create an enabling environment. Accelerating the development of industrial parks—including API and downstream facilities—will further consolidate manufacturing capabilities and foster industrial growth.

Workforce Development

Building a skilled workforce is critical to sustaining industry growth and compliance. Structured internships and apprenticeships in pharmaceutical manufacturing, combined with the development of national curricula covering GMP, automation, digital documentation, and regulatory affairs, will ensure that the sector has a steady pipeline of competent professionals.

Regional Export Expansion

Regional market opportunities through the **ECOWAS Medicines Regulatory Harmonization (MRH)** framework and the **African Continental Free Trade Area (AfCFTA)** remain underutilized. Leveraging these opportunities requires harmonized regulatory systems, export financing schemes through the Bank of Industry (BOI) and Nigerian Export-Import Bank (NEXIM), and the introduction of a **"Made-in-Nigeria PQ-Ready" certification scheme** to enhance competitiveness and facilitate regional and international market access.

6.4 Lessons Learned

Local Manufacturing Capacity Exists—But System Enablers Are Weak

Assessments across ACT, RDT, and LLIN manufacturing reveal that domestic manufacturers possess sufficient installed capacity to meet national demand. However, systemic constraints—including limited access to financing, unpredictable market demand, and regulatory bottlenecks—prevent full utilization of this capacity. Addressing these enablers is critical to translating industrial potential into sustainable production and reducing reliance on imports.

Digital Transformation as a Strategic Enabler

Findings from the regulatory workstream demonstrate that digital systems are transformative for the pharmaceutical manufacturing sector. Digital learning platforms can accelerate workforce competency, while automated documentation systems significantly reduce regulatory delays. Self-regulation supported by digital tools enhances industry credibility and compliance. These insights underscore that the shift toward digital systems is essential, not optional, for modernizing production, governance, and regulatory processes.

Shared Infrastructure Reduces Industry Burden

The assessments identified shared infrastructure—such as API parks, entomology laboratories, LLIN testing facilities, and bioequivalence centers—as essential public goods. Investments in

these assets by government and development partners reduce operational costs for manufacturers, enhance competitiveness, and facilitate compliance with global quality standards.

Predictable Demand Drives Investment

Manufacturers indicated that pursuing WHO PQ certification is only viable if there is confidence in future returns. Multi-year procurement commitments and donor-aligned incentives are therefore essential to stimulate investment in capacity upgrades, quality systems, and product innovation.

Public–Private Coordination Is Critical

Strong coordination mechanisms, including task forces, technical working groups, and engagement with PMG-MAN, demonstrated that multisector collaboration yields better outcomes than isolated interventions. Such coordination ensures that policy, regulatory, and industrial strategies are aligned, promoting a conducive ecosystem for local manufacturing growth.

Compliance Failures Are Often Process-Related

DCE findings revealed that most regulatory submission failures are linked to process inefficiencies rather than technical capacity. Common challenges include poor document organization, lack of standard operating procedures (SOPs), and weak digital systems. This highlights that digital process redesign, alongside targeted training, is essential for improving compliance and reducing delays.

Regional Market Opportunities Are Underutilized

Opportunities for export-oriented growth through the African Continental Free Trade Area (AfCFTA) and the ECOWAS Medicines Regulatory Harmonization (MRH) framework remain largely untapped. Leveraging these regional markets requires harmonized regulatory systems, standardized documentation, and access to export financing.