LOCAL HEALTH PRODUCTS & TECHNOLOGIES MANUFACTURING IN AFRICA:

Ecumenical Pharmaceutical Network (EPN) Perspective

Strengthening Africa's Health Sovereignty Through Faith-Based Pharmaceutical Systems

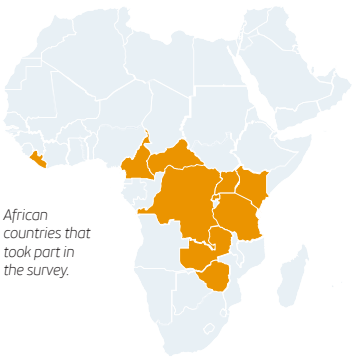
EXECUTIVE SUMMARY

Africa's health sovereignty is contingent on strengthening local pharmaceutical manufacturing, as pandemic-induced supply chain disruptions have exposed critical vulnerabilities. A review of 24 Ecumenical Pharmaceutical Network (EPN) members in 10 countries documents persistent medicine access challenges and systemic gaps. Key things to note is that Faith-based organisations are instrumental in advocacy, procurement, and quality assurance of Health products and Technologies in Africa. This paper calls for concerted, multisectoral action to achieve sustainable production, reduce import dependence, and establish a resilient pharmaceutical ecosystem for the continent.

1. INTRODUCTION

1.1 Background and Context

Africa accounts for 25% of the world's disease burden but produces only 3% of its own medicines. This leaves local healthcare systems dependent on imports and often short on supplies. EPN, an African Based network of faith based health organizations conducted a survey that indicated regular supply chain shortages due to overreliance on imports.



African countries that took part in the survey.

African Union initiatives such as Agenda 2063 and the Pharmaceutical Manufacturing Plan provide strategic guidance. However, progress is slow; by 2024, only 13 countries have fully adopted the AU Model Law on regulatory harmonisation, falling short of stated objectives.

Efforts including AUDA-NEPAD's work on 24 essential products and the local vaccine production goal (60% by 2040) demonstrate momentum. Realizing these targets requires shifting from fragmented initiatives to a coordinated, integrated manufacturing system.

1.2 Methodology

This paper uses a mixed-methods approach to examine Africa's capacity to produce its own medicines. The qualitative part reviews key national and continental policies, such as the PMPA, to identify regulatory and infrastructure challenges. The quantitative part is based on a survey of 24 EPN organisations from 10 countries, looking at procurement, supply chain stability, and progress in local manufacturing. The survey found a 33.4% rate of stock-outs. Data was collected through an administered questionnaire for key people at each organisation.

This method combines big-picture policy analysis with real-world health system challenges. While the survey sample is small, the fact that 91.7% of participants are involved in procurement makes the results more meaningful. By bringing together primary data and grey literature, the study builds a strong base for policy recommendations in the context of growing health sovereignty.

2. PROBLEM STATEMENT

Africa's pharmaceutical industry still relies mostly on imports, with up to 80% of medicines coming from outside the continent. This is due to weak infrastructure, divided markets, and low trust among local stakeholders. About 70.8% worry about the quality of local products, and less than 10% of regulators meet WHO Maturity Level 3. As a result, substandard medicines make up 18.7% of the market.

A shortage of skilled workers (66.7%) and limited research and development hold back local companies, leading to frequent stock-outs that affect more than a third of providers. To move forward, Africa needs better regulatory alignment, local API production, and focused workforce training. If these issues are not addressed, local manufacturing goals will remain out of reach.

KEY DATA

- Africa bears 25% of the global disease burden yet produces only 3% of the world's pharmaceuticals.
- The continent relies on imports for 70% to 80% of finished medicines and a staggering 99.9% of its vaccine needs.
- Over 33% of regional healthcare providers reported facing frequent stock-outs driven by high costs and procurement delays.
- While 70.8% of providers doubt local quality, less than 10% of national regulators meet WHO maturity standards for safety.
- Growth is stifled by a 66.7% shortage of technical personnel and fragmented markets that prevent competitive economies of scale.

3. RESULTS

Research shows that, despite strong healthcare involvement across Africa, there is still reliance on external markets. While 91.7% of EPN members handle procurement, a third still face regular stock-outs, mainly because of the 'import gap.' Africa has 25% of the world's diseases but makes only 3% of its medicines and just 0.1% of its vaccines. Delays in procurement, reliance on imports, and high costs are major reasons for these shortages.

The transition to self-reliance is blocked by these significant hurdles:

1. **Trust Gap (70.8%):**

This represents the single greatest barrier to local market uptake. Frontline healthcare organisations express deep scepticism regarding the consistency of local manufacturing standards, a trust gap that directly limits domestic procurement.

2. **Limited Technical Capacity (66.7%):**

Respondents highlighted a shortage of specialised pharmaceutical scientists, engineers, and regulatory experts, alongside a lack of local Research and Development (R&D) infrastructure.

3. **Higher Production Costs (62.5%):**

Local manufacturers face financial strain due to external factors, including poor logistics, unreliable electricity, and the high cost of importing active pharmaceutical ingredients (APIs), making it difficult to compete with low-priced international imports.

4. **Governance and Accountability Issues (45.8%):**

Nearly half of the surveyed network highlighted that institutional bureaucracy, lack of transparency, and poor governance significantly stall regulatory approvals and disrupt fair market competition.

5. **Market Fragmentation (41.7%):**

Fragmented national markets prevent local firms from achieving the economies of scale needed to reduce production costs, underscoring the urgent need for regional integration through economic blocs.

6. **Weak Regulatory Oversight (37.5%):**

This closely mirrors the broader continental reality, where fewer than 10% of National Medicines Regulatory Authorities (NMRAs) have attained WHO Maturity Level 3. This regulatory capacity gap, failing to adequately police the market directly, feeds into the region's high prevalence of substandard and falsified medicines.

Regulatory and technical weaknesses have allowed substandard medicines to make up 18.7% of the market. Still, everyone surveyed agrees that local manufacturing is key to future strength. With 79.2% of members already buying locally when they can, there is a base for regional growth. Policymakers should align local production with AUDA-NEPAD's 24 Priority Medical Products to help build a more unified and effective manufacturing system.

3. EPN'S POSITION

EPN backs the growth of a strong, fair, and high-quality local pharmaceutical industry in Africa. The goal is to ensure steady access to affordable, safe, and effective medicines, especially for underserved and rural communities supported by faith-based health groups. Using findings from assessments, literature, and surveys, EPN shares these policy positions to guide advocacy and strategy:

1. Reliable access to medicines is a basic public good:

EPN believes that boosting local production is a strong policy answer to frequent stock-outs, which 33.4% of members report, often caused by procurement delays and unstable global supply chains.

2. EPN strengthens systems against substandard and falsified medicines:

With 70.8% of members citing local product quality concerns, EPN positions itself as a quality assurance partner to build trust and ensure compliance within local supply chains.

EPN is dedicated to establishing robust post-market surveillance and pharmacovigilance systems, leveraging member networks to track adverse drug reactions and verify product integrity.

3. Adherence to International Standards (GMP):

EPN supports the phased implementation of World Health Organisation (WHO) Good Manufacturing Practices (GMP) roadmaps to ensure that local facilities can compete globally and provide safe, effective medication to the last mile.

4. Leveraging Faith-Based Networks for Market Stability

Strategic Local Procurement: EPN advocates that its members who already procure locally (79.2%) adopt a formal procurement strategy to prioritise locally manufactured essential medicines, thereby providing a stable, predictable market for regional producers.

Last-Mile Accessibility: EPN asserts that faith-based organisations are uniquely positioned to ensure the benefits of local manufacturing reach underserved and rural areas, thereby overcoming the urban-centric distribution bias noted in the current literature.

Since 41.7% of members say limited market size is a challenge, EPN supports working together regionally and pooling manufacturing efforts within groups. This approach can help make local production more sustainable and profitable.

5. Harmonisation of Regulations

EPN calls for harmonizing medicine registration and regulatory processes across borders to reduce fragmentation within pharmaceutical distribution systems in theprivate-sector and facilitate the free movement of quality-assured medicines.

6. Investment in Technical Capacity and Human Resources

Bridging the Skills Gap: To address the 66.7% concern regarding limited technical capacity, EPN positions itself as a facilitator for capacity-building partnerships for pharmaceutical personnel.

Promotion of R&D: EPN advocates for increased government and private investment in local Research and Development (R&D) to move beyond simple formulation and into the production of Active Pharmaceutical Ingredients (APIs) and other raw materials.

EPN urges governments to remove industry barriers to local manufacturing companies to enable local companies to compete with global pharmaceuticals and thrive in Africa. .

7. Leveraging the EPN Network to Accelerate the Domestication of the AU Model Law

EPN mobilises its network of 149 members across 38 countries as advocates for the strategic domestication and implementation of the African Union (AU) Model Law on Medical Products Regulation, fostering a harmonised and supportive legislative environment.

5. RECOMMENDATIONS

Drawing on research, the Pharmaceutical Manufacturing Plan for Africa, and the EPN survey, we outline the following main steps to accelerate local pharmaceutical manufacturing in Africa. These actions are meant to help the continent move from relying on imports to achieving lasting health independence.

1. Prioritise High-Impact Medical Products

To make local manufacturing successful and improve public health, production should focus on high-demand products with clear health benefits.

Focus on the AUDA-NEPAD 24 Priority Products: Align investments with the identified list of essential medicines, including maternal health products (Oxytocin), NCD treatments (Insulin), and infectious disease therapies (Amoxicillin, Malaria treatments).

National and regional leaders should work toward the African Union's goal of making 60% of vaccines locally by 2040. This includes handling all steps of production, from making the drug substance to the final product.

2. Strengthen Regulatory Frameworks and Quality Assurance

It is essential to close the trust gap. 70.8% of stakeholders see quality assurance as the main barrier to using locally made medicines. Policy and advocacy can this issue to build a strong local manufacturing sector.

Operationalise the African Medicines Agency (AMA): Member states are encouraged to accelerate operationalization of AMA to harmonise standards across borders, reducing the cost and time required for regional market entry.

Achieve WHO Maturity Level 3: National governments are encouraged to provide technical and financial support to National Medicines Regulatory Authorities (NMRAs) to reach international standards, ensuring that locally produced medicines are globally competitive and eligible for export.

Regulatory reliance pathway: This optimises resources and expedites patient access to safe medications by avoiding duplicative scientific reviews.

3. Implement Strategic Procurement and Market Integration

For 41.7% of organisations, a divided market is a big challenge. Building a single, reliable market is key to long-term success.

Adopt Strategic Local Procurement Policies: National Health Ministries should implement Local First procurement strategies, using long-term framework contracts and guaranteed purchase agreements to provide a stable market for local producers.

Leverage Regional Pooled Procurement: Use the African Continental Free Trade Area (AfCFTA) and regional blocs, including ECOWAS, COMESA, SADC, UMA, CEN-SAD, ECCAS, to pool demand, enabling manufacturers to achieve the economies of scale needed to lower prices and compete with international imports.

4. Invest in Human Capital and Technology Transfer

Since 66.7% of respondents reported lack of sufficient technical skills in the manufacturing of health products and technologies, developing the workforce is necessary for growth.

Global partners and investors should shift focus from simple packaging to the local production of Active Pharmaceutical Ingredients (APIs), other raw materials and complex therapeutics.

Governments and academic institutions should collaborate to create specialised training programs in pharmaceutical engineering, regulatory science, and Good Manufacturing Practices (GMP).

5. Provide Fiscal and Infrastructure Incentives

High production costs are a problem for 25% of the market. Governments need to create a supportive economic environment to help lower these costs.

Establish digitalised Specialised Pharmaceutical Zones: Provide manufacturers with plug-and-play infrastructure, including reliable, subsidised electricity and dedicated logistics hubs, while addressing the geographical challenges.

Offer tax holidays, eliminate tariffs on imported raw materials/machinery, and create pharmaceutical bonds or low-interest credit lines specifically for manufacturing expansion.

6. Mitigate Supply Chain Disruptions

To reduce stock-outs, which affect 33.4% of providers, the supply chain needs to be more local.

Organisations should systematically transition from international procurement to local sourcing for essential medicines to bypass the logistics delays and currency fluctuations that drive disruptions.

Use the unique reach of faith-based and community organisations to deliver locally produced medicines to rural and underserved populations, ensuring last-mile access.

7. Promote Reverse Engineering for Indigenous Technology Development

To overcome the 66.7% technical capacity deficit, Africa can prioritise the reverse engineering of off-patent medical products. Leveraging TRIPS flexibilities through the AU Model Law enables regional hubs to legally replicate vital formulations and machinery. This catalyses a transition from basic packaging to domestic API synthesis, building a skilled indigenous workforce and securing self-reliant pharmaceutical technology.

8. Drive Strategic Legislative Engagement

EPN calls on national parliaments to accelerate the domestication of the AU Model Law on Medical Products Regulation to address the 37.5% regulatory oversight gap. Having parliamentary legislators to champion for harmonisation of regional standards, dismantle bureaucratic bottlenecks, and establish the legally binding frameworks required to incentivise and protect local pharmaceutical investments.

CONCLUSION

The evidence in this paper shows that Africa's healthcare system is at a turning point. Relying on imports for 70% to 80% of medicines and almost all vaccines is not sustainable for a continent aiming for real health independence.

Reaching the goal of a self-sufficient pharmaceutical sector takes more than just growing the industry. It needs a united effort across different sectors. By putting the African Medicines Agency (AMA) into action, focusing on AUDA-NEPAD's 24 priority medical products, and using faith-based networks to build trust in quality, Africa can move from basic production to advanced, full-scale manufacturing.

By working together on the recommendations in this paper from aligning regulations to supporting local procurement Africa can build the strength needed to handle global challenges and reach the goals of **Agenda 2063: The Africa We Want.**

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About EPN:

The Ecumenical Pharmaceutical Network (EPN) is a Christian, international, non-profit organization established in 1981 dedicated to improving access to medicines and enhancing the quality of pharmaceutical services, particularly in church-based healthcare systems. Our mission is rooted in compassion and justice, and we strive to ensure that everyone has access to affordable, quality medicines and pharmaceutical services. With its secretariat based in Nairobi, Kenya, EPN serves over 300 million people across Africa and beyond.

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