Policy Brief:

The role of the AfCFTA in scaling up Pharmaceutical Manufacturing and Trade in Africa

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1. Background[1]

Africa's pharmaceutical industry presents significant opportunities for growth, improved public health outcomes, and economic development under the African Continental Free Trade Area (AfCFTA). However, the sector faces many challenges, such as limited manufacturing capabilities, low intra-African trade levels, and a lack of coordination across initiatives. This policy brief reviews the current landscape of pharmaceutical manufacturing and trade and provides recommendations that will aid in scaling up pharmaceutical manufacturing and trade using the platforms created by the implementation of the AfCFTA.

The recent establishment of the AfCFTA provides an enabling framework to increase levels of pharmaceutical manufacturing and trade across the continent. Currently, Africa's pharmaceutical manufacturing capabilities remain limited, with 80% of production concentrated in 8 countries and mostly focused on finished formulations, which still require the import of production inputs and equipment. There is limited manufacturing capacity of production inputs such as active pharmaceutical ingredients (APIs) and excipients. Intra-African trade in pharmaceuticals is less than 20% of total imports, hindered by fragmented markets, inefficient logistics and supply chain infrastructure, and lack of harmonised regulatory frameworks. The COVID-19 pandemic further exposed the vulnerabilities of Africa's pharmaceutical supply chains and the urgent need to build resilience and self-reliance.

In recent years, there has been a proliferation of initiatives aimed at strengthening Africa's pharmaceutical sector, including the African Union's Pharmaceutical Manufacturing Plan for Africa (PMPA), the African Medicines Regulatory Harmonization (AMRH) programme, including the establishment of the African Medicines Agency (AMA), Partnership for African Vaccine Manufacturing (PAVM), which has now been transformed into the Platform for Harmonized African Health products Manufacturing (PHAHM), the African Pharmaceutical Technology Foundation, and various other national and regional efforts. There has been a multitude of conferences, reports, policy briefs and dialogues related to topics impacting the pharmaceutical sector, including pharmaceutical manufacturing and regulatory harmonisation. This includes the 2nd World Local Production Forum, organised by the World Health Organization in 2023, which made recommendations to strengthen the local manufacturing ecosystem in Africa.

In addition, several public-private and private-private partnerships have been announced to boost local pharmaceutical manufacturing. Development agencies also continue to focus on various initiatives to support local manufacturing, including events and conferences, thought leadership, feasibility studies, capacity building projects and direct support to local manufacturers. However, these initiatives often operate in silos, with limited coordination and alignment of resources and priorities across projects and markets.

Section 2 of this policy brief summarises the landscape analysis of the sector and identifies key issues and constraints in the sector. Section 3 proposes policy recommendations resulting from the landscape analysis as well as stakeholder consultations. Section 4 focuses on the role of AfCFTA and proposes a high-level implementation road map. Section 5 discusses potential monitoring and evaluation efforts around the road map.

[1] This briefing led by the Nelson Mandela School of Public Governance has been supported by ODI's Supporting Investment and Trade in Africa (SITA) programme, funded by the UK Foreign, Commonwealth & Development Office (FCDO). All views provided are those of the authors and not the responsibility of the FCDO.

2. Landscape analysis

A comprehensive analysis of Africa's pharmaceutical manufacturing and trade landscape (based on a landscape analysis report and stakeholder consultations) reveals the following key findings:

***Manufacturing capabilities*:** Africa has approximately 600 pharmaceutical manufacturers, most of which are small-scale and focused on finished formulations. These manufacturing facilities are concentrated across 20 countries, with 8 countries accounting for about 80% of local production. API and excipient production is limited, with most inputs imported from abroad. Key challenges include high costs of production input, utilities and equipment used for manufacturing, skills gaps, and difficulty accessing affordable financing. Information gaps include comprehensive mapping of production capacity and capabilities across markets.

***Intra-African trade*:** Pharmaceutical trade between African countries remains low, accounting for less than 20% of the continent's total pharmaceutical imports. Barriers include fragmented markets, disparate regulatory regimes, tariffs on inputs, inefficient customs and border procedures, lack of mutual recognition of regulatory standards and inconsistent enforcement of country-specific regulatory requirements.

***Policy frameworks*:** The AfCFTA and the PMPA provide overarching policy frameworks to support pharmaceutical sector development and trade. However, implementation at national levels has been slow and inconsistent, in the absence of overarching, binding, supranational legal frameworks. There is limited alignment between industrial and health policies. Furthermore, lack of regulatory harmonisation has been cited as a key barrier for further sector development – this is being addressed by the establishment of the African Medicines Agency (AMA). All these policy initiatives contribute to the overall governance of the pharmaceutical sector.

Coordination challenges: The proliferation of pharmaceutical initiatives and projects has led to fragmentation and in some cases, duplication of efforts. Lack of coordination between continental, regional, and national bodies hinders progress and results in inefficient use of scarce resources. In addition, broad stakeholder engagement, that includes the private sector in the design, development and implementation of these initiatives, is often lacking.

***Demand-side challenges*:** Procurement of pharmaceuticals in Africa is often fragmented, unpredictable, and skewed towards imported products. Procurement agencies do not prioritise the procurement of locally manufactured products. Lack of alignment between local manufacturing ambitions and procurement practices of national health systems, development partners and international procurement mechanisms undermines sector growth and penalises local manufacturers. Lack of recognition of certain regulatory approval standards by global procurement agencies further exacerbates market access challenges for local manufacturers. This in turn negatively impacts the sustainability of local manufacturing.

3. Policy recommendations:

Our analysis and consultations suggest the following policy recommendations:

***Regional value chain development*:** The AfCFTA calls for the development of regional value chains, including for the pharmaceutical sector. These value chains need to be informed by a comprehensive mapping of markets in terms of their pharmaceutical manufacturing capabilities, production volumes, workforce skills and comparative advantages to identify strengths, gaps, priority product categories and potential contribution to the efficiency and competitiveness of the pharmaceutical value chain. These insights should be used to develop evidence-based and regionally differentiated industrial policies and investment plans to promote investment and competitiveness and avoid duplication of efforts across markets. Scope of manufacturing should go beyond addressing public health emergencies and should prioritise essential medicines as well as innovative medicines for disease priorities.

***Pooled procurement*:** The continental pooled procurement mechanism, African Pooled Procurement Mechanism (APPM), led by the Africa Centres for Disease Control and Prevention (Africa CDC), should be prioritised for implementation for essential medicines, in partnership with national government health departments as well as multilateral, continental, , regional and national procurement agencies. Aggregated demand across countries, through the implementation of pooled procurement mechanisms, should prioritise locally produced medicines that meet quality, safety and efficacy standards. These mechanisms will provide market visibility and predictability to local manufacturers for the purposes of production planning, which in turn will contribute towards sustainability and security of supply. Development finance institutions should be engaged to provide offtake guarantees and working capital to local manufacturers. Procurement entities should plan and prepare for paying potentially higher prices for locally manufactured products initially to support the local manufacturing ecosystem to ensure that the local manufacturing sector reaches economies of scale in a reasonable timeframe.

***Co-ordination mechanisms*:** A high-level coordination mechanism under the leadership of the AfCFTA Secretariat should be established to align the various pharmaceutical sector initiatives focused on the development of regional value chains through research and development (R&D), manufacturing and trade to pool resources, drive a unified strategy, and avoid duplication across continental bodies, regional economic communities, member states, development partners and the private sector. These coordination mechanisms should consider integration into the broader global pharmaceutical manufacturing ecosystem. Regular multi-stakeholder dialogues to guide implementation and monitor progress should be convened. These should be aligned with the efforts of the World Local Production Forum, led by the WHO and any other similar efforts and initiatives.

***Capacity building programmes*:** Pharmaceutical manufacturing capacity building programmes, which include key stakeholders such as the United Nations Economic Commission for Africa (UNECA), the United Nations Industrial Development Organization (UNIDO), African Pharmaceutical Technology Foundation, academia, private sector, amongst others, should be coordinated by the AfCFTA Secretariat, as far as possible, to strengthen institutional expertise, execution capabilities and optimise resources at continental, national and regional levels. Programmes should include current and relevant training curricula, organised peer learning and mentorship initiatives based on needs that aim to futureproof capacity building as far as possible in the face of rapidly evolving technologies. Financial and technical assistance should be sourced where required.

***Value chain approach to regulatory harmonisation*:** Regulatory harmonisation beyond the scope of oversight by National Medicines Regulatory Authorities, should be prioritised to facilitate pharmaceutical trade across markets. This would require alignment of standards and requirements across regulatory and government agencies that have oversight into other aspects of the pharmaceutical value chain, e.g. harmonisation of product standards, customs and border control requirements, tax and tariff regulations. Model implementation roadmaps should be developed for member states to aid domestication of harmonised regulations and standards. Technical assistance is needed to streamline and digitalise regulatory processes across the value chain, with a particular focus on manufacturing and trade.

***Tariff and non-tariff barriers*:** A high-level AfCFTA task force should be established to review and address trade barriers impacting pharmaceutical manufacturing, including tariffs on production inputs, non-tariff barriers (NTBs), and import-export procedures. AfCFTA guidelines to address NTBs should be created, based on an inventory of NTBs that are specific to the pharmaceutical sector.

***Sector financing initiatives*:** An AfCFTA-led financing initiative for pharmaceutical manufacturing, in collaboration with development finance institutions, investment banks and other financing institutions, should be established to improve access to capital for local manufacturers to upgrade facilities, expand production, and invest in R&D. There are several funds that have been created by development partners and pan-African financing and development institutions to support pharmaceutical sector development (such as initiatives by GIZ, the Gates Foundation and African Development Bank). These initiatives should be coordinated and aligned to the overall mandate of the AfCFTA to create regional value chains in the pharmaceutical sector to ensure optimal use of resources, avoid duplication and to leverage opportunities for collaboration.

4. Implementation roadmap for the AfCFTA

Appendix Table 1 maps these recommendations onto the trade and investment provisions in the AfCFTA Agreement. The recommendations can leverage the AfCFTA as an overarching framework to drive strategic coordination, capacity building, policy harmonisation, and multi-stakeholder engagement to scale up pharmaceutical manufacturing and trade across Africa.

To operationalise these recommendations, the following actions should be taken:

1. ***High level coordination meeting*:** Convene a high-level coordination meeting with the African Union Commission, AfCFTA Secretariat, Africa CDC, regional economic communities RECs, academia, private sector representatives, including international and local players, and other relevant stakeholders to align on priorities and to establish a joint pharmaceutical sector workplan.

   Requires strong political commitment and leadership to ensure sustained engagement and follow-through from all parties involved.

2. ***Supply-side mapping*:** Commission a study to conduct a supply-side and pharmaceutical manufacturing mapping, with a clear scope of work, timeline, and budget. Engage industry associations, private sector, regulatory agencies, trade and health ministries in the design and validation of the mapping. The study should include experts in pharmaceutical manufacturing, industrial policy, and trade and should consider dependencies and integration into global value chains.

Complex due to the need for comprehensive and reliable data across multiple countries and the potential for data gaps or inconsistencies. The study should employ a robust methodology and allocate sufficient time and resources for completion.

3. ***Technical working group for pooled procurement*:** Support the implementation of the African Pooled Procurement Mechanism (APPM) as a key priority to drive market access for local manufacturers. A technical working group on pooled procurement, led jointly by the Africa CDC and AfCFTA Secretariat, should be established comprising of representatives from national, regional and continental health and finance authorities, procurement agencies, regulatory agencies, development partners and the private sector.

   Need to balance varying national interests, global, national and regional procurement systems, and legal frameworks. The working group will need to build trust and consensus among participants and work towards developing governance frameworks, operating procedures, financing models and national implementation plans that consider and align with existing procurement practices and legislation.

4. ***Capacity-building needs assessment*:** Conduct a capacity-building needs assessment that targets national medicines regulatory authorities, pharmaceutical manufacturers, procurement agencies, customs authorities, academia, development partners and other key stakeholders. Use the findings to design targeted training programmes, peer learning events, and on-the-job mentorship placements.

   Primarily involves collecting and analysing information from various stakeholders. The challenge will be achieving meaningful response rates. Design training programmes that are relevant, practical, and sustainable and should consider evolving needs, technologies and the issue of brain drain from the continent.

5. ***Financing initiative*:** Engage development finance institutions (such as Afreximbank and the African Development Bank) and other partners to design blended finance instruments to de-risk pharmaceutical manufacturing projects. Explore opportunities for local currency financing, credit enhancements, and risk-sharing agreements. Financing initiatives should include investment criteria, application procedures, and technical support services for local manufacturers.

   Need to mobilise significant financial resources and to design investment instruments that are attractive to local manufacturers, while ensuring financial sustainability and impact. Finance institutions will need to work closely with industry stakeholders and technical experts who understand the complexity of current and future pharmaceutical manufacturing capabilities and requirements.

6. ***Study on trade and investment barriers:*** The AfCFTA Secretariat should commission a study on trade and investment barriers affecting pharmaceutical manufacturing, trade and investment, including a review of tariff schedules, non-tariff measures, and trade facilitation bottlenecks. Use the findings to develop a prioritised action plan to address trade and investment barriers.

   Challenge will be to obtain accurate and up-to-date information on tariff schedules and non-tariff barriers and to build consensus on the prioritised action plan. It will be critical to gain insights from the private sector to understand how trade barriers impact their business operations, in particular local manufacturing and export of finished products to other markets.

7. ***AfCFTA Pharmaceutical sector guidelines:*** Establish a legal experts' working group to draft sector-specific AfCFTA guidelines for pharmaceutical manufacturing, procurement, and trade. Guidelines should align with existing continental policy frameworks, including the AfCFTA Agreement and protocols, PMPA, AU Model Law. Workshops should be hosted to support member states in adapting and adopting these guidelines for incorporation into national implementation plans.

   The legal experts' working group will need to ensure that the guidelines and legislation are compatible with existing national and regional frameworks for ease of adoption, adaptation and implementation.

8. ***Best practices online portal*****:** Create an online portal, managed by the AfCFTA Secretariat, to share market data, best practices, case studies, and policy tools for promoting pharmaceutical manufacturing, trade and regional value chain integration. The portal should include data on trade and investment barriers at member state level. Member states and industry stakeholders should be encouraged to contribute content and participate in peer learning activities.

   Challenge will be to ensure regular updates and active participation from member states and industry stakeholders. There is potential to tag this onto the AfCFTA Country Business Index initiative.

9. ***Multi-stakeholder engagement strategy*****:** Develop a multi-stakeholder engagement strategy, including a calendar of regular dialogues, consultation mechanisms, and communication channels. Assign focal points within the AfCFTA Secretariat to manage stakeholder relations and feedback loops.

   Requires dedicated resources and coordination to maintain regular dialogues and consultation mechanisms. The AfCFTA Secretariat will need to appoint focal points to champion the strategy, build trust and demonstrate responsiveness to stakeholder feedback.

The actions proposed above will require resource mobilisation, both financial and human, and a clear division of responsibilities among the various stakeholders involved. The AfCFTA Secretariat should develop a detailed implementation plan, with timelines, budgets, and monitoring frameworks, to guide the execution of these actions in a coordinated and transparent manner. Some of the AfCFTA protocols are directly relevant to addressing major barriers to trade and investment in Africa (see Appendix Table 2).

The complexity of each action underscores the need for a phased approach, with clear priorities and milestones, and for continuous monitoring and adjustment based on lessons learned and evolving needs. The proposed actions vary in their feasibility and complexity, depending on factors such as political will, institutional capacity, financial resources, and stakeholder buy-in.

5. Monitoring and Evaluation

To track progress and adapt implementation based on lessons learned, a robust monitoring and evaluation framework should be established. Key performance indicators may include:

- Number of countries adopting AfCFTA-aligned pharmaceutical policies and guidelines.
- Value and volume of intra-African trade in pharmaceuticals vs baselines figures over time.
- Number of pharmaceutical manufacturing projects approved, financed and implemented.
- Proportion of essential medicines procured from African manufacturers vs imports, based on supply-side and pharmaceutical manufacturing mapping (this could also include tracking growth in market shares of local manufacturers).
- Number of regulatory staff trained and achieving competency benchmarks across the value chain, including port health and customs authorities, procurement and finance agencies.

The AfCFTA Advisory Council should oversee implementation, review progress reports, and recommend course corrections as needed. An independent evaluation should be commissioned at midpoint and at the end of implementation to assess the impact and to identify areas for improvement.

6. Risks and Mitigation strategies

Implementing these recommendations will not be without challenges. Key risks to anticipate and mitigate include:

***Political risks*:** Changes in government leadership, priorities and overall political stability in member states are risks to implementation. Lack of policy coherence between ministries, vested interests and conflicting mandates could undermine implementation. Sustained high-level dialogue, strategic communications, and inclusive stakeholder engagement and policy coherence will be critical.

***Capacity risks*:** Limited human and institutional capacities could hinder execution and absorption of technical assistance towards harmonising and domestication of harmonised standards to address trade and investment barriers. Partnerships with development partners, universities, training institutes, and the private sector can help build a robust talent pipeline. Phased implementation and adaptive implementation approaches can balance local manufacturing ambitions with market conditions. Training and capacity-building initiatives should be designed with long-term sustainability in mind.

***Financing risks*:** Mobilising adequate and sustained financing for pharmaceutical manufacturing projects will be an ongoing challenge, particularly in fiscally constrained environments. Other environmental challenges, including supporting infrastructure and complex business operating environments will impact market attractiveness. Proactive engagement of development finance institutions, private investors, and development partners from the outset can help de-risk financing. Input from technical experts who understand pharmaceutical manufacturing will be critical. Domestic resource mobilisation strategies should also be explored to reduce external dependencies.

***Regulatory risks*:** Resistance to regulatory reforms and harmonisation efforts could limit the free movement of pharmaceuticals across borders. Sensitisation of policymakers, regulatory agencies, industry stakeholders, and the general public on the benefits of common regulatory regimes across the value chain and across borders in Africa will be important. Phased implementation of convergence plans and dispute resolution mechanisms can help build trust and alignment. Regulatory risks should be viewed and addressed with the lens of unintended public health consequences.

7. Conclusions

Scaling up pharmaceutical manufacturing and trade in Africa is a complex undertaking that will require sustained political commitment, policy coherence, multi-stakeholder collaboration, and mobilisation of significant financial and technical resources to create sustainable growth and development of the sector. The AfCFTA provides a timely and powerful framework to drive major parts of this agenda forward, but success will depend on effective coordination, evidence-based policies, and inclusive implementation based on accurate, up-to-date and relevant data.

By mapping manufacturing capabilities, strengthening regulatory harmonisation, pooling procurement, and building capacity at all levels, African countries can accelerate the growth of a globally competitive pharmaceutical industry that enhances access to quality-assured medicines, creates jobs, and saves lives. The recommendations and roadmap presented in this brief provide a foundation for action but will need to be adapted and owned by stakeholders across the continent. With visionary leadership, shared purpose, and collective action, Africa can realise the promise of its pharmaceutical manufacturing and trade ambitions in the years ahead.

Appendix Table 1: Linking key policy suggestions to provisions and actions under the AfCFTA

	AfCFTA Secretariat	**AfCFTA Phase 1 Trade rules**		**AfCFTA Phase 2 Trade rules**	**Other**
AfCFTA areas: (policy suggestions from landscape paper)	Awareness creation	Tariffs, non-tariff barriers / rules of origin	Services	Investment / intellectual property rights / competition	Dispute settlement / Digital / Instruments (e.g. Adjustment fund)
Clearly define regional integration and regional value chains	Yes, Secretariat to explain role in developing RVCs				
Private-private partnerships for APIs & excipient manufacturing				Protocol on Investment may help to attract investment	
Improve institutional capacity for intra-Africa trade of pharmaceuticals	Support AfCFTA national implementation committees (to implement trade policies)	Good implementation of standards			
Address tariff and non-tariff barriers to pharmaceutical trade		Deal with NTBs, reduce tariffs on imports for production inputs			
Market access	Pooling procurement		Financial services		
Regulatory reliance model implementation	Supporting African Medicine Agency	Harmonising regulation			
Value chain approach to regulatory harmonisation	Co-ordinating actors		Value chain approach	Value chain approach	

Source: Own.

Appendix Table 2: Linking key policy suggestions to provisions and actions under the AfCFTA

	Trade rule	Objective	Policy recommendations from landscape analysis
AfCFTA trade rules: Phase 1	Tariff reductions and eliminations	Members commit to reducing and eventually eliminating tariffs on 90% of goods traded within the continent over a period of 5 to 10 years. Some sensitive goods are allowed longer tariff reduction periods	Reduce and eliminate tariffs on imported production inputs to support local manufacturing
	Rules of origin	Establishing rules to determine the origin of goods traded within the AfCFTA to prevent non-members from benefiting from the agreement	
	Trade facilitation	Implementing measures to simplify and streamline customs procedures, to reduce non-tariff barriers, and to enhance trade facilitation mechanisms to promote smoother trade flows	Address tariff and non-tariff barriers to pharmaceutical trade; Implement regulatory reliance model; Support the implementation of the African Medicines Agency (AMA)
	Customs cooperation and mutual assistance	Promoting cooperation between customs authorities to improve enforcement, combat smuggling, and address trade-related challenges	Improve institutional capacity for intra-Africa trade of pharmaceuticals; Upskill customs and border authorities to combat substandard and falsified products
	Trade in services	Frameworks for liberalising trade in services, including provisions for market access, national treatment, and regulatory cooperation	Develop frameworks to support development of allied services sector to support local pharmaceutical manufacturing
	Dispute settlement mechanisms	Establishing procedures for resolving disputes between member states regarding the interpretation or application of AfCFTA rules	
	Transparency and institutional framework	Setting up mechanisms for transparency, information sharing, and monitoring of trade-related policies and measures	Implement value chain approach to regulatory harmonisation beyond marketing authorisation
	Intellectual property rights (IPR)	Addressing intellectual property rights issues to promote innovation, technology transfer, and protection of intellectual property within the AfCFTA	Promote the use of tech transfer agreements between international and local players

	Competition policy	Developing competition policies and regulations to ensure fair competition and prevent anti-competitive practices within the AfCFTA	Write a protocol on Investment to help to attract investment
	Investment protocol (yet to be finalised)	Negotiating rules and regulations for investment within the AfCFTA framework to facilitate investment flows and promote economic integration	Utilise investment protocol to attract investments in the sector through public-private and/or private-private partnerships for API & excipient manufacturing; Develop allied industries that will support the local pharmaceutical manufacturing sector
AfCFTA trade rules: Phase 2	**Trade rule**	**Objective**	**Policy recommendation**
	Further tariff reductions and eliminations	Continuing tariff reductions and eventually eliminating tariffs for remaining goods not covered in Phase 1	Further reduce and eliminate tariffs on imported production inputs to support local manufacturing
	Services liberalisation	Deepening commitments on trade in services, including additional sectors and modes of supply	
	Investment rules	Finalising the Investment Protocol to facilitate investment flows, protect investors, and promote economic development	Support AfCFTA national implementation committees (to implement trade policies)
	E-commerce	Developing rules and regulations for e-commerce to facilitate digital trade and enhance connectivity across the continent	n/a
	Intellectual property rights (IPR) enforcement	Strengthening enforcement mechanisms and regulations related to intellectual property rights to foster innovation and protect creators	Ensure that international investors are assured of intellectual property protection of their patented medicines
	Competition policy	Further developing competition policies and regulations to ensure fair competition and prevent anti-competitive practices	Clearly define regional integration and value chains in the pharmaceutical sector to promote economic development, growth and competitiveness
	Government procurement	Establishing rules for government procurement to promote transparency, fair competition, and efficiency in public procurement processes	Establish supra-national rules for government pooled procurement of medicines and facilitate market access for local manufacturers
	Trade remedies	Establishing mechanisms for addressing unfair trade practices, such as anti-dumping measures, countervailing duties, and safeguards	Further strengthen institutional mechanisms for customs and border controls to curb influx of parallel import, sub-standard and counterfeit medicines

	Customs cooperation and trade facilitation	Continuing efforts to improve customs cooperation, to streamline procedures, and to reduce non-tariff barriers to trade	Establish a value chain approach to harmonised regulations for customers and border controls to facilitate regional trade of pharmaceuticals to increase intra-African trade levels
	Dispute settlement mechanisms	Enhancing procedures for resolving disputes between member states and ensuring the effective implementation of trade agreements	