Collaborate to promote pharmaceutical trade and sustainable practices with COMESA

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COMESA Regional Trade Facilitation Programme and Green Pharmaceutical Manufacturing Strategy

AHMTEC – 2025

8th October 2025

Agenda

- Opening Remarks
- COMESA Trade Facilitation Programme
  - Introduction to the study and its objectives
  - Pre-liminary insights on pharmaceutical trade across Africa
  - Open discussion: stakeholder experiences and ideas for improvement
- Green Pharmaceutical Manufacturing in COMESA
  - Environmental compliance findings
  - Strategic recommendations and way forward
  - Q&A and stakeholder reflections
- Conclusion

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Africa's over-reliance on pharmaceutical imports warrants development of a sustainable local pharmaceutical industry to fulfill the needs of its population

Why there is a need of sustainable local pharmaceutical industry development and trade facilitation?

1. Over-reliance on pharmaceutical imports

- Africa accounts for only **3%** of global pharmaceutical manufacturing.
- Sub-Saharan Africa imports **~70-80%** of its pharmaceutical needs**.**
- Only **8 African countries account** for 80% of the total pharmaceutical production.
- Although COMESA region is vast with **21 member States**, domestic pharmaceutical industry is **small and underdeveloped**.
- In 2020, the value of pharmaceuticals imports in the region amounted to **USD 5.6 billion** while the exports amounted to only **USD 457 million**

2. Post Pandemic challenges and opportunities

- **COVID-19** pandemic left Africa facing a unique set of challenges:
  - **Emergence of infectious diseases** and non-communicable diseases (NCD)
  - **Disruption in the supply chain** making it difficult for essential medicines to reach Africa
- This translated into the **need for the local pharmaceutical industry** to reduce external dependency.

3. Identifying existing 'Green Practices'

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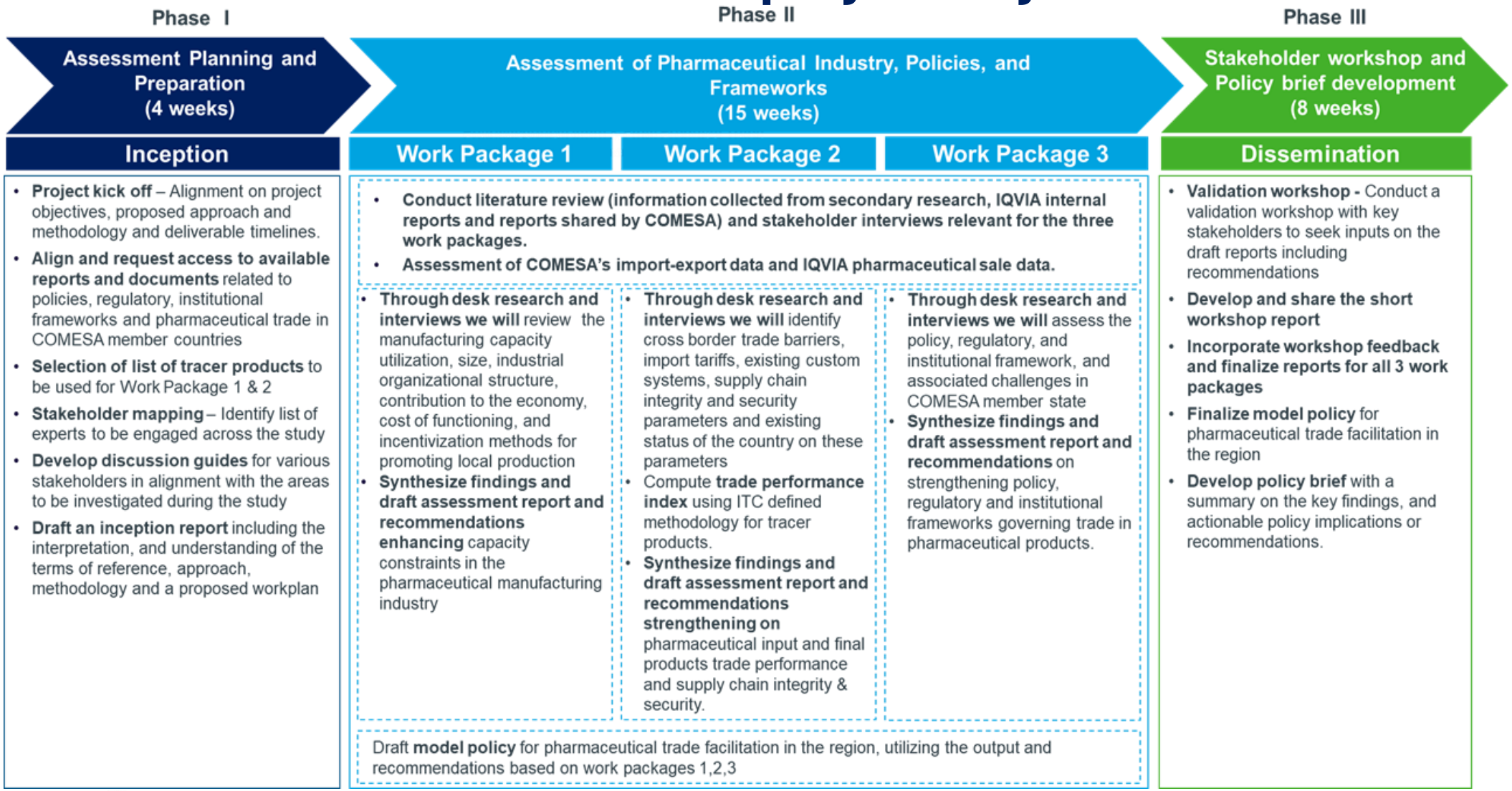
The project aims to enhance capacities, trade policies, and supply chain integrity to develop a reliable local pharmaceutical industry

Objectives	Assess existing opportunities and constraints	Recommendation
	Capacity Constraints • To assess the capacity constraints in pharmaceutical manufacturing	**Capacity Constraints** • Measures to enhance investment, local manufacturing, optimize capacity utilization, and enhance supply chain integrity
	Pharmaceutical Products Trade Performance • To assess the pharmaceutical input and final products trade performance and supply chain integrity	**Pharmaceutical Products Trade Performance** • Measures to enhance trade, integrity, and security of regional supply chains of pharmaceutical input and products
	Policy, Regulatory and institutional Framework • To assess policy, regulatory and institutional frameworks governing trade in pharmaceutical products and develop a model policy for trade facilitation in the region	**Policy, Regulatory and Institutional Framework** • Measures to improve policy and regulatory formulation and institutional reforms/establishments to support trade in pharmaceutical products and inputs

We proposed a three phased approach to successfully conduct the assessment and deliver the project objectives



Post COVID-19, shifts have been made to expand local manufacturing capacity, facilitate trade through enabling policies and regulations; further opportunities exist to improve trade performance

Pharmaceutical trade

Manufacturing capacity

- **High manufacturing capacity** (Egypt, Kenya and Tunisa), **growing industry** (Uganda, Ethiopia) facilitated by strong **import-substitution policies** and **government support**
- Majority of production is focused on **generics** (such as antibiotics & analgesics)
- Most manufacturers operate **below installed capacity** (<30-40%)
- There is significant potential for growth in **capacity building, R&D**, especially for diseases prevalent in Africa (malaria, TB, HIV, NCDs) e.g., Rwanda is launching health informatics and pharmaceutical sciences programs to build local expertise

Import vs Export

- **100% of APIs are imported:** these include paracetamol, amoxicillin, artemether/lumefantrine (antimalarial), and tenofovir (HIV), among others.
- Largely imports constitute **finished pharmaceutical products** from India (generics, essential), China (APIs, medical devices), Switzerland (oncology, branded, and other special drugs).
- **Kenya** is the **primary exporter** within the region, particularly to other **East African** markets, Egypt exports more to North and West Africa (and globally)
- **Intra-African trade** in pharmaceuticals is **low** (~3% of total import value). Ethiopia engages in trade of hard gelatin capsules with other African countries.

Policies & regulations

- **National-level pharmaceutical policy** – more countries increasingly formulating industrial policies for the pharma sector promoting import substitution and local manufacturing (e.g., Ethiopia, Kenya, Uganda)
- **African Union's Pharmaceutical Manufacturing Plan for Africa (PMPA)** – provides a high-level framework to build local production and reduce imports
- **Within AfCFTA** – member states are exploring external tariff regime for pharmaceuticals to incentivize local manufacturing, while keeping raw inputs duty-free
- **African Medicines Agency (AMA)** – provides a continental framework to further harmonize and potentially centralize certain regulatory functions

Factors influencing pharmaceutical trade in the African/COMESA region

Customs procedures

- **Customs clearance processes** have been streamlined with automation and "single window" system; however, some countries still rely on manual processes and duplicate process by different regulators (e.g., Burundi)

Supply chain, logistics & infrastructure

- **Distribution and cold chain facilities** across borders is crucial for trade; regional logistics integration. e.g., for Rwanda transport of pharmaceuticals through the Northern Corridor has reduced transit times
- **Warehousing and inventory management** through the implementation of digital systems for real-time tracking

Trade incentives & disincentives

- Introduction of policy incentives such as **import duty waivers** on pharmaceutical inputs, **tax holidays**, or **public procurement preferences** for local manufacturers to encourage local production. e.g., procurement price preferences in Kenya and investments in industrial park in Ethiopia
- Disincentives to trade in the form of **cumbersome administrative procedures, import quotas, and protectionist measures**. e.g., Zimbabwe and Ethiopia have at times restricted public tenders only to local producers or imposed higher fees on foreign products. In Rwanda, National Monitoring Committees actively engage to eliminate NTBs.

Trade facilitation instruments

- **Key initiatives** include:
  - **One-Stop Border Posts** [Kenya-Uganda; Rwanda - Uganda & DRC];
  - Rwanda Electronic **Single Window** and Kenya's TradeNet allow traders to submit all import/export documentation through **one portal**;
  - Authorized Economic Operator programs in Rwanda, Kenya, Uganda, and Zambia to recognize **high compliance traders** and fast-track clearance procedures.

Topic 1: Navigating the AfCFTA: From policy to practice

Rationale

The AfCFTA is defining trade framework for broader access to African market, yet its practical application for pharmaceutical manufacturers is unclear. Address the real-world hurdles manufacturers' face, providing critical insights into the specific NTBs and policy gaps that need to be addressed

What have been your direct experiences (positive or negative) with customs, tariffs, and Rules of Origin when trying to export to other African countries under the new AfCFTA-guided protocols?

Which specific Non-Tariff Barriers (e.g., import permits, inspections, and administrative delays) are most costly and time-consuming for your business in intra-COMESA trade?

From your perspective, what is the single most important change in trade facilitation policy that RECs could champion to make the AfCFTA a commercial reality for you?

Topic 2: The Future of Regulation: AMA, Harmonization, and Gaining Trust

Rationale

Regulatory hurdles are a primary driver of cost and a significant barrier to market access. With the AMA about to be operational, it is crucial to understand manufacturers' perspectives on how regional harmonization can best support their growth.

How much does navigating divergent national registration requirements currently cost your company in terms of time and money for a single product across African markets?

What are your biggest concerns and hopes regarding the operationalization of the African Medicines Agency (AMA)? What specific functions should it prioritize to help your business?

What kind of support from regional bodies would best help national regulatory authority achieve a higher WHO maturity level?

Topic 3: Boosting local production: The Role of Special Economic Zones (SEZs) and Supply Chain Resilience

Rationale

Increasing local manufacturing capacity is a core objective for Africa. Special Economic Zones (SEZs) are emerging as a key strategy to overcome systemic challenges like poor infrastructure and high input costs. This topic directly addresses the how-to" of expanding production and strengthening regional supply chains.

Beyond finance, what are the top three operational bottlenecks (e.g., API sourcing, skilled labor, utility costs) that currently limit your ability to increase plant capacity utilization?

What specific incentives (e.g., tax holidays on imported raw materials, guaranteed government off-take, streamlined land acquisition, dedicated utilities) would make locating a new production line within a pharmaceutical-focused SEZ an attractive proposition for your company?

How can we better integrate regional logistics solutions, like the COMESA RCTG scheme, into the SEZ model to ensure seamless supply chain integration from API import to final product export?

Topic 4: Unlocking investment and innovation: Accessing new funding and technology

Rationale

Understanding gap between available development and trade finance and manufacturers' ability to access the funds is significant in success of industry development and facilitation trade

What are the biggest challenges you have faced when trying to secure long-term financing for trade, capital expansion or equipment upgrades?

Are you aware of the new financing facilities from institutions like the AfDB and Afreximbank? What information or support would you need to successfully apply for these funds?

If the African Pharmaceutical Technology Foundation (APTF) could help you acquire the technology and license to produce one product you currently do not make, what type of product would it be and why?

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COMESA, through the African Development Fund, aims to support pharmaceutical sector development in the region

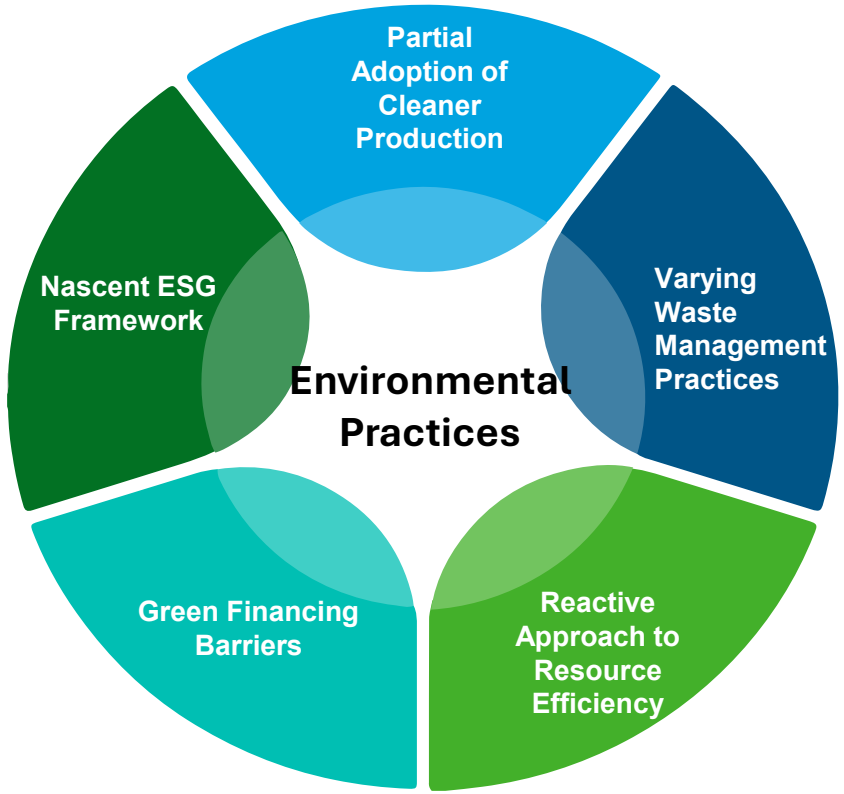
Scope and objective

Objectives

Assessment	Recommend
Environmental Compliance Assess compliance status of the pharmaceutical sector to environmental regulations in relation to manufacturing standards, packaging, storage, transportation & disposal of pharmaceutical products	**Environmental Compliance** Develop technical and policy recommendations to improve the compliance of the pharmaceutical sector in the COMESA region
Good Manufacturing Practices Assess current GMP status of the region and outcomes of initiatives led by regional groups for regulatory harmonization	**Good Manufacturing Practices** Develop a COMESA wide Good Manufacturing Practices roadmap based on an analysis of the current GMP status of the region
Local Pharmaceutical Industry Assess existing pharmaceutical industry policies, capacity, strengthens weaknesses, opportunity, and threats	**Local Pharmaceutical Industry** Develop a 10-year COMESA Green Pharmaceutical Manufacturing Strategy and Business Plan

Today's discussion will be focused on the outcomes of the environmental compliance assessment, proposed recommendations and way forward

Across COMESA region environmental regulatory landscape is strong on paper but fragmented and weak in practice



Partial Adoption of Cleaner Production

Foundational practices are present, but wider adoption of green chemistry requires targeted regional incentives.

Varying Waste Management Practices

Basic hazardous waste segregation is in place, while advanced treatment for API residues is limited.

Reactive Approach to Resource Efficiency

Efficiency initiatives are primarily reactive and cost-driven, with limited use of sustainable packaging.

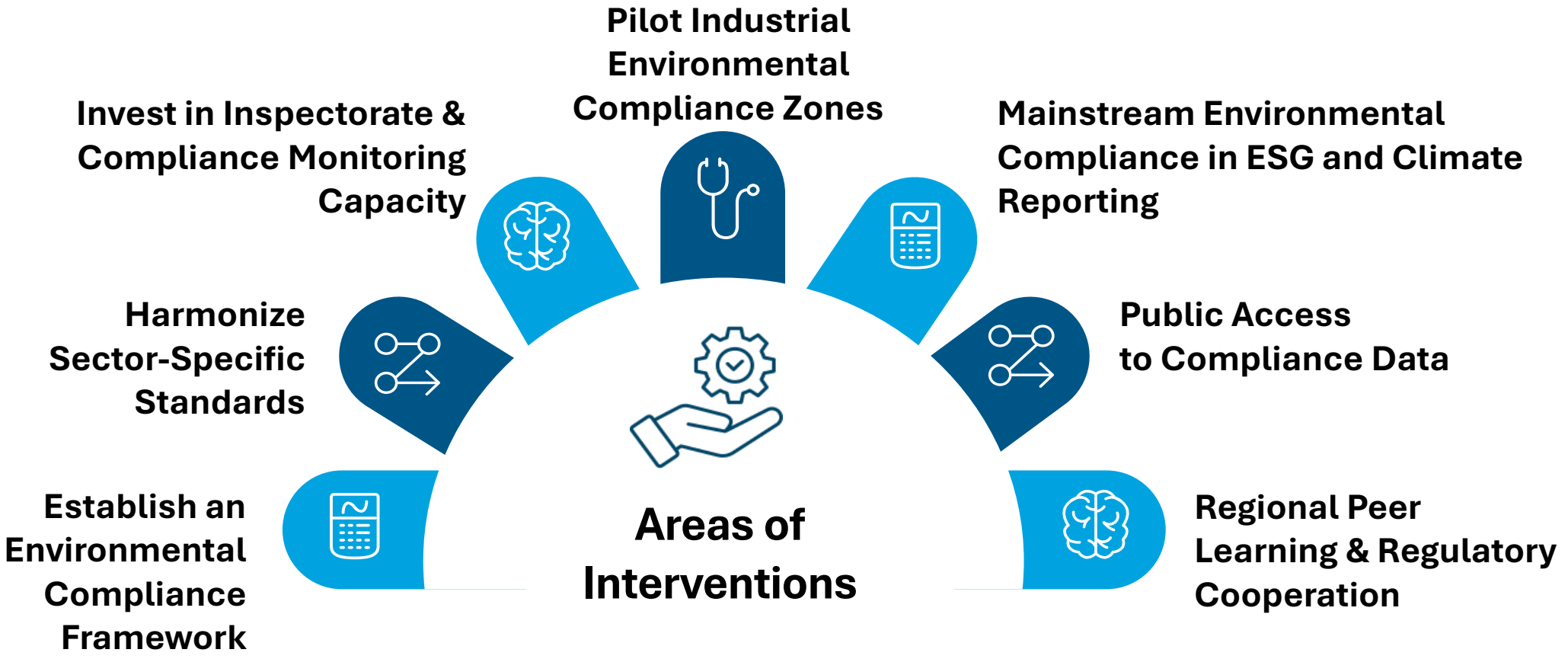
Nascent ESG framework

ESG Framework integration is externally driven by export client demands, not embedded in internal governance

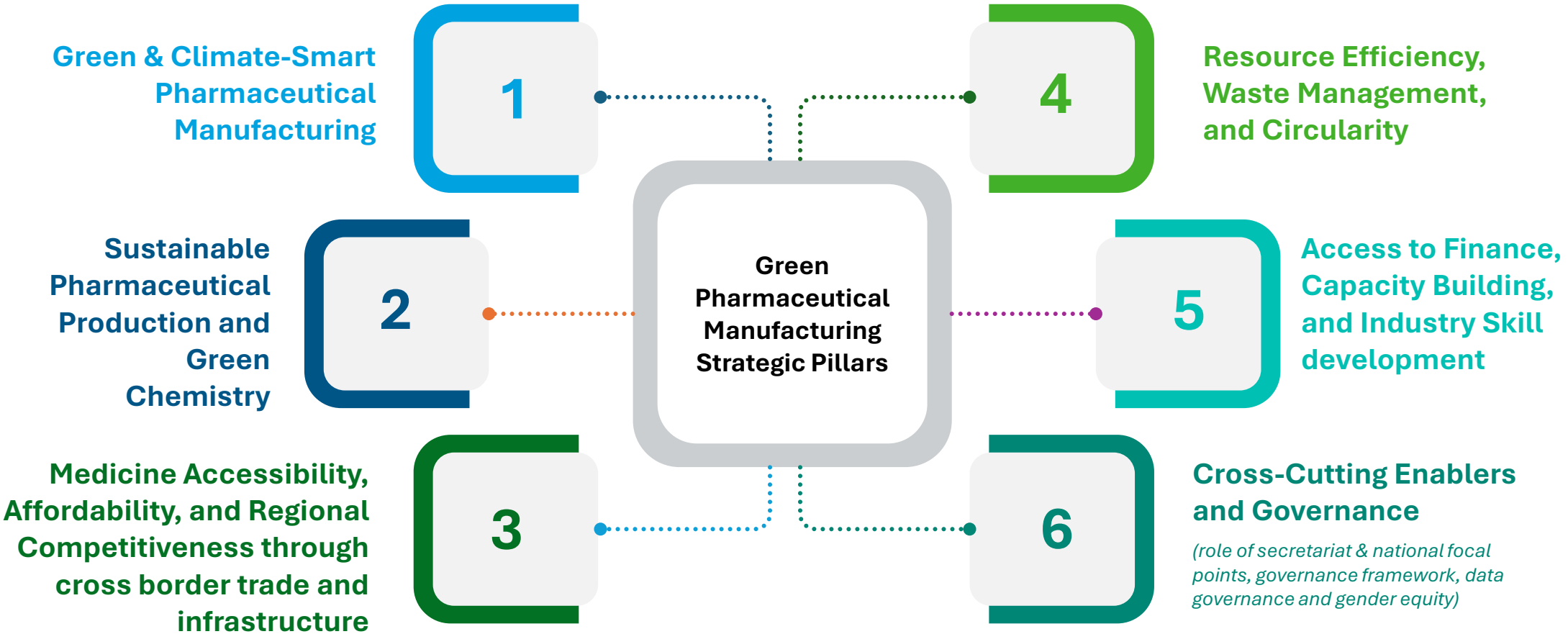
Green Financing Barriers

Manufacturers highlighted challenges in accessing green loans or climate-aligned credit

A strategic shift is needed from reactive, approval-driven environmental governance to a proactive, transparent, and integrated system



COMESA has identified six strategic pillars considered critical to promote “Greening” and facilitate trade in the region



Open Discussions

How can governments incentivize private sector investment in sustainable manufacturing technologies while ensuring affordability and access?

How can the region adopt and enforce green certification standards without creating additional regulatory burdens?

What role can digital platforms and e-learning hubs play in democratizing technical knowledge across the region?

How can manufacturers balance environmental compliance with cost competitiveness in a resource-constrained setting?

How can African countries attract ESG-aligned capital and integrate pharmaceutical manufacturing into broader climate finance frameworks?

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Thank you