Support to Africa’s Pharmaceutical Industry: 2030 Vision and Action Plan

AfDB
Strategic Objectives: “High 5’s”

AfDB "High 5" goals

Light up & power Africa

Feed Africa

Industrialize Africa

Integrate Africa

Improve quality of life

AfDB industrialization objectives

Play a leading and pivotal development role in Africa

Support global trade integration and regional value chains

Grow co-financing and mobilize private sector investment

Foster the emergence of regional champions

Create sustainable jobs and increase productivity

Key principles of AfDB industrialization strategy

Impactful

- Focus on areas where AfDB can deliver highest economic, social and environmental impacts

Catalytic

- Be a renown leader in Africa & a pulling force for additional investments and partners

Differentiated

- Adopt a differentiated sector and country approach with a variety of intervention tools

Actionable

- Push pragmatism in project identification, pursue concrete opportunities & clear roadmap

Fact-based

- Analyze value chains to identify opportunities and bottlenecks
Prioritization: Industrial sectors with highest impact

**Differentiated approach with 3 tiers (2020)**

<table>
<thead>
<tr>
<th>15 addressable sectors</th>
<th>Filtering process criteria</th>
<th>Differentiated approach</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICT</td>
<td>Apparel</td>
<td>&quot;Tier 1&quot; sectors: aggressive business development</td>
</tr>
<tr>
<td>Pharma-ceuticals</td>
<td>Textile (CTG)</td>
<td>Investigated in detail</td>
</tr>
<tr>
<td>Gas Beneficiation</td>
<td>Consumer Goods</td>
<td>To address in priority</td>
</tr>
<tr>
<td>Agro-processing</td>
<td>Retail</td>
<td>&quot;Tier 2&quot; sectors: proactive monitoring</td>
</tr>
<tr>
<td>Mining</td>
<td>Automotive</td>
<td>Sector analysis</td>
</tr>
<tr>
<td>Hospitality</td>
<td>Machinery &amp; Equipment</td>
<td>To monitor</td>
</tr>
<tr>
<td>Building materials</td>
<td>Metals manufacturing</td>
<td>&quot;Tier 3&quot; sectors: addressed opportunistically</td>
</tr>
<tr>
<td></td>
<td>Consumer Durables</td>
<td>Industry snapshot &amp; long list of companies</td>
</tr>
<tr>
<td></td>
<td>Chemicals &amp; Petrochemicals</td>
<td>To address reactively</td>
</tr>
</tbody>
</table>

- **Additionality of AfDB and link with other 'High 5'**
- **Ability to play and to foster "champions"**
  - Starting point / competitive advantage
  - Potential regional champions
- **Alignment with public policies currently launched in African countries**
- **Catalyst impact and ability to trigger the development of other sectors**
- **Macroeconomic impact**
  - Job creation potential
  - Revenue creation potential
  - Impact on Trade balance
  - Sustainability of future trends

Sectors in which AfDB will have a systemic approach – including through sectoral reform.
Rationale

- The COVID 19 pandemic has exposed the fragility of health systems and highlighted the necessity of countries’ ensuring at least a minimum level of security of supply for health products.
- Like many governments globally, some governments in Africa are thinking of developing local pharmaceutical sectors: mostly for security of supply but also potentially to make medicines more affordable to patients, to release the pressure on the balance of payments, and to create wealth more broadly.
- The development of the African pharmaceutical industry is limited by structural challenges such as small and fragmented markets, logistical constraints, tariff and non-tariff barriers, and limited know-how.
- African production falls well short of local demand; on average 30–40% of demand is produced locally, with very diverse levels of manufacturing maturity among the different countries.

Objectives of the Study

Define a action plan to support the development of Africa’s pharmaceutical industry:
1. Provide a clear diagnostic of the current African pharmaceutical market in terms of maturity and size as well as an overview of supply and demand dynamics.
2. Set an ambition for the African continent in terms of local production by 2030 and beyond.
3. Define AfDB’s vision, model of intervention per cluster, to support the development of a robust local pharmaceutical industry.
4. Structure an industrial policy support and investment roadmap, composed of a pipeline of strategic initiatives and quick wins, examples of projects, and a communication plan.
Deliverables of the Study

1. Diagnostic

- Understanding the pharmaceutical industry (e.g., demand, supply, distribution, attractiveness to foreign investment, regulation, quality and standards, competitiveness against imports) and benchmarking of country/region success stories in the pharmaceutical sector
- Benchmarking support interventions and financing instruments of multi-laterals/regional development banks to develop the pharmaceutical sector
- Clarifying the possible models of intervention and financing instruments at the disposal of the Bank
- Clustering countries and products into homogeneous categories (e.g., therapeutic areas)

2. Strategic approach

- Defining the ambition for Africa’s local pharmaceutical production
- Clarifying the Bank’s vision and approach for the pharmaceutical sector by 2030 and identifying a toolkit for the Bank to use to support the development of the sector (e.g., modes of intervention, financing instruments), including for vaccine manufacturing
- Developing a 5-year action plan including:
  - Priority regions and segments to target
  - List of short and long term initiatives with detailed action plans

3. Preparing for implementation

- Defining a sequenced roadmap for the identified initiatives including the resources required
- Recommending transformative flagship programs cover all the aspects of pharmaceutical vision
- Identify concepts of potentially bankable investment opportunities
- Preparing a communication plan with different stakeholders including internal and external stakeholders, Regional Member Countries (RMCs) and the private sector, etc.
Key facts about the global pharmaceutical industry

1. An industry with high margins, but highly dependent on economies of scale and very risky
   - Average EBITDA margin for global pharmaceutical labs (~30%) vs. ~7% in automotive for example
   - 30% to 50% of the COGS are production cost, requiring sufficient scale to ensure the cost competitiveness of the production units
   - 10–15 years on R&D process for patented drugs, with a probability of success below 15%

2. Total pharmaceutical market amounts to 1,200 bn USD, polarized around mature markets, with growth coming from generic products and oncology
   - ~60% polarized around the US and Europe, while Africa represents only ~2%
   - ~3.5% growth rate for generic products driving the market expansion, while patented drugs are slowly growing at 1.5%
   - ~25% of the world total demand is driven by oncology products, growing at ~8% vs. ~2% market growth

3. Generics market is characterized by a fragmented competitor landscape, diverse product mix, and growth coming from emerging markets
   - Top 10 companies capturing less than 30% of market share, resulting in a sustained fragmented market without consolidation of share
   - ~8% growth rate of emerging countries leading the generics market expansion, while the US and Europe still concentrate ~40% of the total market
Overview and trends of the African pharmaceutical market

1. The US$25 bn African pharmaceutical market is underpenetrated, with diverse geographic dynamics

- Total sales are concentrated in Northern African countries, and Eastern and Western Africa driving the 5.2% future growth until 2024

2. The African market concentrates around 3 main therapeutic areas, which drive its growth with generic products

- +3.1% growth rate of generic products, supporting the African market expansion

3. Innovative technologies and products (e.g., biosimilars, oncology) represent a growing but still limited market in Africa

- ~40% of the total sales are generic products, lower than in generics-driven markets like China and India (~70%)

- Innovative type of products (biosimilars and oncology) are the fastest growing technologies in terms of demand in Africa

- ~40% growth rate of biosimilar products during the last 4 years, while representing ~10% of the market sales

- ~6% growth rate of biosimilar products during the last 4 years, while representing ~10% of the market sales

4. The epidemiological profile of the continent is moving towards a higher share of non-communicable diseases and injuries

- ~50% of Africa's disease burden polarized around communicable disease (e.g., HIV/AIDS, respiratory infections and tuberculosis)

- By 2030, non-communicable diseases are expected to represent ~45% of the continent’s disease burden, a clear shift in the continent epidemiological profile

- Top 10 countries representing ~75% of the total market
Diagnostic of the African local pharmaceutical manufacturing capacities

1. Africa has limited manufacturing capacity, concentrated in a few countries, and is less competitive than benchmarks.
   - 30–40% of the total demand volume is locally produced in Africa.
   - ~80% of total production is concentrated in 8 countries.
   - Acceleration: Of acquisitions and greenfield projects of the past 5 years.
   - ~60% higher cost per unit observed in Africa than in China and India.

2. African companies show a low level of integration along the value chain, with limited to no R&D and API production capacities.
   - ~90% of the pharmaceutical companies operating in Africa are focusing on manufacturing and packaging activities.
   - Less than 2% of worldwide pharmaceutical R&D projects are happening in Africa.
   - Less than 20% of manufacturers producing APIs are operating in Africa, compared with ~400 in India and China.

3. The local production capacities focus mainly on simple manufacturing processes, generics and demand-driven therapeutic areas.
   - 80–90% of African pharmaceutical companies are focusing on solid oral and liquid/gel forms.
   - ~70% of the local manufacturing capacities are dedicated to generics production.
   - ~85% of the local production is focused on the top 6 ATCs, which represent >70% of the total demand.

4. Several barriers decrease local pharmaceuticals manufacturers’ competitiveness and prevent the development of new actors.
   - 6 main barriers hinder local manufacturers, including the lack of supportive policies, protection or preferential access to markets, regulatory approval and pricing.

5. Several barriers decrease local pharmaceuticals manufacturers’ competitiveness and prevent the development of new actors.
   - 7 main barriers hinder local manufacturers, including the lack of supportive policies, protection or preferential access to markets, regulatory approval and pricing.
   - Of these companies have achieved WHO pre-qualification status, illustrating the difficulties African manufacturers face in achieving high quality standards.
Seven strategic orientations arose from a comprehensive diagnostic and informed the thinking around the development of the pharmaceutical industry in Africa.

1. Potential to further develop the African Pharmaceutical Industry...
   - Clear potential to develop African pharmaceutical manufacturing capacities, for strategic, public health and economic reasons.

2. Mid-sized local and international pharmaceutical companies have increasingly shown interest in increasing their manufacturing capacities within the continent.

3. Solid forms of generics seem to be the primary focus for further development of local production in most African markets; however, more complex forms and products can help increase local production in more mature markets.

4. Fragmented market with countries showing limited demand emphasizing the need to create pharmaceutical hubs in some regions to attain sufficient scale.

5. Logistic integration needs to be strengthened to foster the development of regional hubs and enable efficient intra-African and international trade.

6. The harmonization of sector quality standards from education to manufacturing to distribution is necessary to enable sustainable growth of the African pharmaceutical industry.

7. Limited R&D activities that should increase to address specific needs related to African disease burden and heterogeneous genetic pools compare to the rest of the world.

Strategy pillars and enablers:

1. Increase the maturity of the industry by supporting the development of local production capacities.

2. Enable regional logistic integration.

3. Help the implementation of quality industry standards.

4. Seed the creation of R&D capacities.
We adopted a two-level thinking process from defining an ambition for the continent, to identifying how AfDB is uniquely positioned to support the industry.

1. Africa’s pharmaceutical strategy

- Thinking around a strategy to unlock the potential for the pharmaceutical industry in Africa including:
  - A realistic **ambition for local production capabilities by 2030**
  - 1 strategic pillar and 3 enablers supporting the ambition

2. African Development Bank’s support opportunities

- Identification of **potential investment opportunities for the African Development Bank** to foster the development of the local pharmaceutical industry
- Prioritization of the investment opportunities identified based on the African Development Bank’s comparative advantages
A sustainable path to the pharmaceutical industry would necessarily be a combination of these 3 strategic options

The suggested path is a combination of the 3 stylized strategic options

- **An industry aiming to achieve self-sufficiency**

- **An industry mostly anticipating the epidemiological transition of Africa**

- **An industry focusing on molecules that match the current epidemiological profile**

- **Focusing mostly on security of supply for products where African can be truly competitive**, e.g. generics in oral solid forms

- **Targeting products and molecules to respond to the increase in NCD**, in particular on products and molecules that are not much of interest to other parts of the world

- **Increasing R&D capacities** to prepare for the upscaling of the industry and to address the specific heterogeneity of the continent

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1. Non-Communicable Diseases

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Developing a sustainable industry could be possible by **combining the economic impact of security of supply with the public health advantages of addressing the new disease burden (NCD), while increasing R&D capacities**.
A target of 45-55% (70% of essential molecules) of local production would be highly ambitious yet achievable by gathering a diversity of partners around the agenda.

### Target as % of local production by 2030

<table>
<thead>
<tr>
<th>Equivalent in units</th>
<th>Ambition level</th>
<th>Achievability</th>
</tr>
</thead>
<tbody>
<tr>
<td>~115-120 Bn</td>
<td>Highly ambitious target matching the levels observed in developed countries and BRICS with an increase of 30pp vs. today (~30-40%)</td>
<td>Very large investments required from all public and private players (&gt;USD220 Bn)</td>
</tr>
<tr>
<td>~85-90 Bn</td>
<td>Very ambitious target, adding ~15pp vs. today’s level of local production</td>
<td>Protectionist measures to be put in place, putting at risk patients’ access to medicines</td>
</tr>
<tr>
<td>~60-65 Bn</td>
<td>Status-quo target, in line with today’s level of production (~30-40%) with basic needs not being covered</td>
<td>Significant investments required from both public and private sector (~USD110 Bn)</td>
</tr>
</tbody>
</table>

### Achievability

- **Low investments required (<USD15 Bn)**
- **High investments required (>USD220 Bn)**
- **Significant investments required (~USD110 Bn)**

The target could be achieved by focusing on **30 identified molecules in generics oral form**

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1 60-70% in Japan, 70-80% in the US, 75-85% in China investment
2 Estimated by expert for an targeted increase twice vs. the selected path
3 As detailed in the strategy
4 Assuming no infrastructure
30 potential molecules could be considered for local production given their importance in terms of market demand, public health, and their availability in a generic form.

High potential molecule analysis methodology

~1850
Molecules analyzed covering 14 ATC

~80
Molecules with market sales >60M\(^1\) USD (2019)

~35
Focus on high health priority molecules recommended by local agencies, WHO and health experts\(^2\)

30
Focus on molecules available in generic forms

Non Exhaustive List

Detailed analysis on key markets (North, South, Eastern and Western Africa)

Inputs from expert interviews (internal and external)

1 Market sales allowing for economic viability for potential manufactures. ~80 molecules covering ~50% of total market in sales

2 Priority given to high African disease burdens. Duplicate drugs further shortlisted to account for therapeutic area diversification

2030 targets have been defined for the Strategic Pillar and the 4 Enablers

**STRATEGIC PILLAR**
Increase the maturity of the industry by supporting the development of local production capacities

- **1. Support the development of local manufacturers on essential molecules to serve their local markets**
  - Targeted production of local manufacturers: ~8-9 Bn units
  - Number of African companies producing biosimilars, i.e. X3

- **2. Foster the expansion of African and mid-sized international companies on essential molecules within selected countries**
  - Targeted production of mid-sized global and Af. champions: ~11-13 Bn units

- **3. Help mature pharmaceutical companies diversify their product portfolio and technologies**
  - Number of African companies producing biosimilars, i.e. X3

**ENABLER I**
Enable regional logistic integration to foster intra-African trade and the creation of trade hubs
- Intra-African pharma exports to USD1 Bn by 2030, i.e. +70%

**ENABLER II**
Help the implementation of quality industry standards for the African continent
- Of all pharma manufacturers adhering to GMP standards: ~20%

**ENABLER III**
Seed the creation of R&D capacities focusing on Africa specific diseases and needs
- Pharmaceutical R&D investment in the continent by 2030, i.e. +50%

**ENABLER IV**
Pave the way for increased vaccines manufacturing on the continent
- Continent platforms supplying a significant share of the needs

**Value in 2019**
**2030 target**
- Share of local production in value by 2030: 30-40% → 45-55%
- Number of African companies producing biosimilars, i.e. X3

Source: TradeMap, UNECA, World Bank, WHO, IQVIA
The Strategic Pillar will aim at increasing the maturity of the industry by supporting the development of local production capacities.

**Context**
Africa heavily relying on imports with local production capacities addressing only 30%-40% of the local demand in value.

**Rationale**
- Clear potential to develop additional African pharmaceutical manufacturing capacities for strategic, public health, and economic reasons.
- Growing interest from mid-sized local and international pharmaceutical companies to increase their manufacturing capacities within the continent.

**Ambition**
Reach 45%-55% share of local production in value by 2030.

### Strategic axis KPIs

<table>
<thead>
<tr>
<th>Description</th>
<th>Baseline</th>
<th>Aspiration levels</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Local manufacturers current production sites capacity upscaling</strong></td>
<td>~8.5 Bn units</td>
<td>~13 Bn units</td>
</tr>
<tr>
<td><strong>New production lines capacity of local manufacturers</strong></td>
<td>N.A</td>
<td>~7 Bn units</td>
</tr>
<tr>
<td><strong>Upscaling of current production capacity operated by mid-sized International companies and transnational champions</strong></td>
<td>~14 Bn units</td>
<td>~16 Bn units</td>
</tr>
<tr>
<td><strong>Creation of new production lines operated by mid-sized international companies and transnational champions</strong></td>
<td>N.A</td>
<td>~15 Bn units</td>
</tr>
<tr>
<td><strong>Number of African manufacturers producing biosimilars</strong></td>
<td>5</td>
<td>10</td>
</tr>
<tr>
<td><strong>Africa biosimilar production capacity</strong></td>
<td>~25 Mn units</td>
<td>~40 Mn units</td>
</tr>
</tbody>
</table>

**Description**
- Increase African local manufacturers’ production capacity focusing on solid oral form products by:
  - Upscaling existing manufacturing capacities of local manufacturers to reach their full potential.
  - Creating new manufacturing production sites to meet local demand.
- Promote the expansion of African regional champions as well as attract mid-sized international companies by:
  - Helping African champions and mid-sized international companies to reach full potential on current solid oral forms production line.
  - Encouraging both players to develop new production sites focusing on solid oral forms.
- Upscale African champion manufacturers capacities on high-tech biosimilar products to serve local and neighboring countries’ demand.
- Attract mid-sized global companies with biosimilars product in their portfolios to localize part of their production in Africa.

**Rationale**
- Clear potential to develop additional African pharmaceutical manufacturing capacities for strategic, public health, and economic reasons.
- Growing interest from mid-sized local and international pharmaceutical companies to increase their manufacturing capacities within the continent.

**Ambition**
Reach 45%-55% share of local production in value by 2030.

**Source:** Expert interviews
With fragmented trade and inconsistent logistics/freight capacities in Africa, defining 4 pharmaceutical hubs could enable to facilitate pharma trade integration.


Source: Expert interviews
Enabler I will aim at improving regional logistic integration to foster intra-African trade and the creation of trade hubs

Context
Despite multiple free-trade agreements, Africa remains very fragmented as trade integration is low across the continent, especially across regional blocks. Intra-African exports are limited by poor internal connection and high transport cost. Distribution is fragmented in some regions, and dominated by international players in others.

Rationale
Enable intra-regional trade through logistic and regional integration to support the emergence of hubs aggregating fragmented markets to attain sufficient scale. Foster intra-African integration to enable exports from the most mature pharmaceutical markets to the rest of the continent.

Ambition
Increase intra-African pharma exports to USD1 Bn by 2030, ~70% increase from USD600 Mn in 2019.

Strategic axis KPIs

<table>
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<th>Description</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Accelerate the intra-regional and intra-continental trade integration through deeper regional collaboration and ratification of a continental-wide trade agreement</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Create regional hubs and identify their potential nerve centers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Select key projects to foster through technical or financial support</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Develop logistic infrastructures and connections for the different regional hubs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Support the development of local distributors to enable the emergence of a balanced competitive landscape in the key markets</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Foster the development of regional6 distributors able to serve regional hubs</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Strategic axis KPIs</th>
<th>2020</th>
<th>2025</th>
<th>2030</th>
</tr>
</thead>
<tbody>
<tr>
<td>UNECA average trade integration index of the 11 top potential nerve centers</td>
<td>0.41</td>
<td>0.51</td>
<td>0.63</td>
</tr>
<tr>
<td>Continental average World Bank logistics index</td>
<td>2.52</td>
<td>2.75</td>
<td>3.03</td>
</tr>
<tr>
<td>Number of African regional/continental distributors</td>
<td>0</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Number of local distributors among top 10 of their country</td>
<td>205</td>
<td>35</td>
<td>50</td>
</tr>
</tbody>
</table>

1. In line with today’s value of South Africa, currently ranked 4th on the continent | 2. In 2018 | 3. In line with today’s value of Rwanda | 4. Based on 1 per hub | 5. Expert estimate | 6. Regional = distributing across several countries, vs national = serving only one country

Source: TradeMap, UNECA, World Bank, Expert interviews, Press search
Enabler II will help the implementation of quality industry standards in line with international benchmarks and specific to the African market

**Context**
African pharmaceutical industry rarely meet high quality standards due to a notable shortage of skilled professionals and lack of implementation of high-quality norms
Counterfeit drugs are a huge source of illicit financial flows and contribute to a high public health cost

**Rationale**
There is a significant need to develop local talent, harmonize and improve standards in order to improve industry quality and diminish the counterfeit market
Improvement of industry quality standards is critical to help foster a sustainable environment for growth of the local pharmaceutical manufacturing capacities

**Ambition**
50% of all pharma manufacturers adhere to harmonized GMP standards per region

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**Strategic axis**

**A**
Support development of critical talent throughout the value chain

**B**
Promote the implementation and harmonization of quality standards

**Description**

- **Increase and improve** pharmaceutical industry education by creating adequate training programs (e.g., graduate courses)
- **Increase university-industry collaboration** and build regional centers of excellence
- **Develop new skills through technology transfer and R&D initiatives**
  - Efficient technology transfers with international manufacturers will be critical to build capacities
- **Improve the quality of standards** through the value chain by enforcing compliance to national then regional GXP\textsuperscript{1} standards for all players
- **Strengthen NMRA capabilities** by building capabilities of their personnel and implementing comprehensive QMS\textsuperscript{3} to ensure adequate inspections and assessments
- **Enhance market integration through drug regulatory harmonization** and regulatory policy alignment at regional then continental level

**Strategic axis KPIs**

<table>
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<tr>
<th>Description</th>
<th>Baseline</th>
<th>Aspiration levels</th>
</tr>
</thead>
<tbody>
<tr>
<td>Density of pharmacists per 10,000 people</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Number of pharmaceutical industry education programs</td>
<td>130</td>
<td>200</td>
</tr>
<tr>
<td>Number of pharmaceutical manufacturers adhering to national or regional GMP\textsuperscript{1} norms</td>
<td>100</td>
<td>150</td>
</tr>
<tr>
<td>Number of regions\textsuperscript{2} with harmonized medicines registration regulatory standards</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Number of continental medicine regulatory authority</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

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1 GXP: Good - manufacturing, distribution, laboratory, clinical or regulatory – Practices
2 Regions considered are Northern, Southern, Western and Eastern Africa – EAC has started to establish the EAC medicines agency
3 Quality management system

Source: FIP, WHO, AU, AUDA-NEPAD, Expert interviews, Press search
Enabler III could seed the creation of R&D capacities focusing on African specific diseases and needs

**Context**

Very limited pharmaceutical Research projects initiated in Africa, and poor clinical trials infrastructure compare to the rest of the world

**Rationale**

Necessity to seed pharmaceutical Research and Development investment to tackle the specific disease burden and genetic heterogeneity of Africa

Opportunity to build on the niche expertise developed in the continent for some therapeutic areas and diseases

**Strategic axis KPIs**

<table>
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<tr>
<th>Description</th>
<th>2020</th>
<th>2025</th>
<th>2030</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceutical R&amp;D projects’ budget allocated in Africa</td>
<td>~1.4 Bn USD</td>
<td>~2 Bn USD</td>
<td>~3 Bn USD</td>
</tr>
<tr>
<td>Number of Bio-tech startups based in the continent</td>
<td>&lt;20</td>
<td>~100</td>
<td>~250</td>
</tr>
<tr>
<td>New signed research partnerships between MNCs and African players</td>
<td>N.A</td>
<td>~10</td>
<td>~30</td>
</tr>
<tr>
<td>Clinical trials infrastructures implemented in Africa</td>
<td>~4 000</td>
<td>~5 000</td>
<td>~7 500</td>
</tr>
<tr>
<td>Pharmaceutical ISO accredited service providers for clinical trials labs</td>
<td>&lt;100</td>
<td>~200</td>
<td>~500</td>
</tr>
</tbody>
</table>

**Aspiration levels**

- 2020
- 2025
- 2030

**Ambition**

50% Increase of pharmaceutical R&D investment in the continent by 2030

**Strategic axis**

- Support the development of an ecosystem to foster Research innovation
- Identify healthcare infrastructure required to support drug development (e.g., clinical trial)
Executive Summary – Intervention model of the AfDB for vaccines manufacturing

- **4 shifts in recent years** have triggered the conversation around vaccine manufacturing in Africa, resulting in a **unprecedented excitement and alignment** between public and private stakeholders, due to both health and socioeconomic considerations, (1) **health considerations** (~9.4MM un- or under-immunized children in Africa in 2020, and supply security challenges for COVID-19 vaccines) and (2) **socioeconomic considerations** (crowding-in robust pharmaceutical industries, improving forex and trade balance challenges, and increasing high-skilled employment).

- A pan African mobilization on vaccine manufacturing led by Africa CDC has set an ambitious target to manufacture **60% of Africa’s routine vaccine needs by 2040**, representing 850 Mn vaccines produced locally in 2040 (and $1.4Bn – $3.2Bn in value with an average price of dose of $1.7 - $3.8)

- **Today, the public African vaccines market is worth $1.3Bn (vs $25Bn for Africa pharmaceutical sales) and represents ~4% of global public market value but up to 25% of global public volumes and could reach between ~$2.3Bn and $5.4Bn by 2030 as a result of five key drivers:** (1) increased access, (2) demographics, (3) pricing, (4) transitioning from Gavi, (5) emerging vaccines products and novel technologies.

- **Gavi/ UNICEF Supply Division** plays a significant role in the African vaccines landscape providing secure, long-term contracts for 90% of the market volume.

- **Currently,** less than 1% of Africa’s vaccines needs are manufactured locally, presenting both a **risk** due to geographic and supplier consolidation with many monopolistic situations on different vaccines and an **untapped opportunity** for local manufacturers to enter or expand production.

- **There are 10 existing local vaccine manufacturing players in Africa, mostly concentrated in North Africa, South Africa and Nigeria (vs ~600 players for pharmaceutical manufacturing),** with about 40% engaged in packaging and labeling, and 40% engaged in fill and finish, and a small part engaged in drug substance manufacturing.

- **The target to manufacture 60% of Africa’s routine vaccine needs by 2040 is in the process of being translated in a roadmap,** and some **high-level estimations indicate a need for 5 manufacturing plants with an investment of ~$600Mn – $1.2Bn depending on different scenarios including parts of the vaccines value chain addressed and technologies concerned** (Africa Union and Africa CDC have partnered and announced an investment of $1.3Bn).

- **As a preliminary roadmap for action,** 6 working groups were defined at the Vaccines summit: (i) Agenda-setting and coordination, regulatory strengthening, Demand uncertainty, Access to finance, Talent & Know-how and Infrastructures.

- **Leveraging on those 6 topics,** **3 strategic axis** are likely to be considered regarding their potential impact as an anticipation of what the action plan could be:
  - **Support the development of African manufacturing plants** by mobilizing long-term financing of investment projects through direct lending and/or equity and technical assistance to local manufacturers and co-investors (e.g. IP technical know-how transfer, sourcing).
  - **Shape a vehicle to pool the demand and provide a take-or-pay type of provision for African countries and ensure long-term vaccine offtake agreements,** as well as ensuring a percentage of demand (e.g. 20-40%) will be procured from African manufacturing.
  - **Support the development of hub anchors,** through public contribution to infrastructure and policy, institutional and regulatory advice.

- **AfDB could help shape the vaccines manufacturing industry by leading or building on each of the strategic axis,** in particular with 2 main programs:
  - **Program to upscale and transform African vaccines manufacturers** through direct lending or indirect equity investment and technical assistance (e.g. support in deal-making in IP and know-how transfer) for a budget of $105-235Mn until 2040, to be provisioned in 2030.
  - **Program to support the development of a vehicle to pool the demand for African countries and ensure long-term vaccine offtake agreements** with a take or pay type of provision for a budget of $220-375Mn until 2030, used to advocate for cooperation between partners, to finance the pooling platform through grants and to create a guarantee fund.
### AfDB is supporting Africa CDC agenda led by Partnership for Vaccine Manufacturing

<table>
<thead>
<tr>
<th>Enablers</th>
<th>Key Summit insights</th>
<th>Unique role of the AfdB on vaccines</th>
</tr>
</thead>
</table>
| **Agenda-setting and coordination** | Act now to take advantage of momentum, while establishing long-term political commitment  
Make thoughtful choices for the broader continent  
Break down barriers to flow of vaccines between countries  
Establish vaccine raw materials industries across the continent | None addressable by AfdB |
| **Regulatory strengthening**  | Build regulatory capacity in select vaccine manufacturing countries  
Establish a single regulatory body for Africa  
Harmonize regulatory standards across the continent and match with international regulatory frameworks | None addressable by AfdB |
| **Demand certainty**         | Create long term supply contracts  
Concerted effort required to achieve pooled demand | Potential to establish a pooled procurement mechanism for and secure offtake agreements for locally produced vaccines |
| **Access to finance**        | Have African financiers drive financing with international support  
Ensure adequate support from funders (DFIs, donors, bilaterals, etc.) for project preparation  
Build business cases for vaccine products | Establish dedicated African vaccines manufacturing fund |
| **Talent and know-how**      | Support homegrown talent development, and attract African talent across the value chain (e.g., for R&D, TT)  
Consider multiple approaches to address IP challenges presented by vaccines | Enabler addressed within the pharmaceutical manufacturing strategy |
| **Infrastructure**           | Expand existing vaccine manufacturer and R&D laboratory capacity  
Establish modular and flexible manufacturing capacity for new plants, and upgrade existing plants  
Address intra-Africa infrastructural barriers to promote distribution of African-made vaccines | Invest in vaccine manufacturing facilities  
Support the expansion of the transportation networks |
USD111 Bn investments could be required on the continent by 2030 to help the development of the pharma manufacturing capacities and required infrastructures.

**Investment required in Africa to implement the strategy by period of 5 years, USD Bn**

<table>
<thead>
<tr>
<th>Year</th>
<th>Pharma Industry</th>
<th>Logistics Infrastructure</th>
</tr>
</thead>
<tbody>
<tr>
<td>2025</td>
<td>~50.0</td>
<td>~50.3</td>
</tr>
<tr>
<td></td>
<td>~0.3</td>
<td>~0.6</td>
</tr>
<tr>
<td>2030</td>
<td>~55.0</td>
<td>~50.5</td>
</tr>
<tr>
<td></td>
<td>~3.8</td>
<td>~0.5</td>
</tr>
<tr>
<td></td>
<td></td>
<td>~1.2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>~111</td>
</tr>
</tbody>
</table>

**Pillar and Enablers**

- **Increase the maturity of the industry** by supporting the development of local production capacities
- **Enable regional logistic integration** to foster intra-African trade and the creation of trade hubs
- **Help the implementation of quality industry standards** in line with international benchmarks
- **Seed the creation of R&D capacities** focusing on African specific diseases and needs

1% computed excluding investments in logistics infrastructures (~2-3% including)

Source: TradeMap, UNECA, World Bank, Public library of science, EAC, European Commission Research and innovation, ClinicalTrials.gov, African Society for Laboratory Medicine Research discussion with AfDB team, Expert interview
An investment of ~USD 3.0 Bn may be required from the AfDB by 2030 to help sustainable development of African pharma manufacturing capacities and logistics infrastructure.

### Potential investment by period of 5 years required for each pillar/enabler, USD Mn

<table>
<thead>
<tr>
<th>Pillar and Enablers</th>
<th>2021 - 2025</th>
<th>2025 - 2030</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increase the maturity of the industry by supporting the development of local production capacities</td>
<td>~USD 2 Bn investment on logistics infrastructure that will benefit economic sectors beyond pharma</td>
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