



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

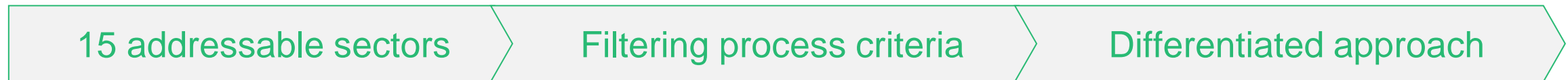
- Push pragmatism in project identification, pursue concrete opportunities & clear roadmap

Fact-based

- Analyze value chains to identify opportunities and bottlenecks

Prioritization: Industrial sectors with highest impact

Differentiated approach with 3 tiers (2020)



| 15 addressable sectors | | | Filtering process criteria | Differentiated approach |
|------------------------|-------------------|----------------------------|--|--|
| ICT ★ | Pharmaceuticals | Textile (CTG) | <p>Additionality of AfDB and link with other 'High 5'</p> <hr/> <p>Ability to play and to foster "champions"</p> <ul style="list-style-type: none"> Starting point / competitive advantage Potential regional champions <p>Alignment with public policies currently launched in African countries</p> <hr/> <p>Catalyst impact and ability to trigger the development of other sectors</p> <hr/> <p>Macroeconomic impact</p> <ul style="list-style-type: none"> Job creation potential Revenue creation potential Impact on Trade balance Sustainability of future trends | <p>1 "Tier 1" sectors: aggressive business development</p> <ul style="list-style-type: none"> Investigated in detail To address <u>in priority</u> |
| Gas Beneficiation | Agro-processing | Consumer Goods | | <p>2 "Tier 2" sectors: proactive monitoring</p> <ul style="list-style-type: none"> Sector analysis <u>To monitor</u> |
| Mining | Hospitality | Retail | | |
| Building materials ★ | Automotive | Machinery & Equipment | | <p>3 "Tier 3" sectors: addressed opportunistically</p> <ul style="list-style-type: none"> Industry snapshot & long list of companies To address <u>reactively</u> |
| Metals manufacturing | Consumer Durables | Chemicals & Petrochemicals | | |

★ 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.

A Key facts about the global pharmaceutical industry

1 An industry with high margins, but highly dependent on economies of scale and very risky



2 Total pharmaceutical market amounts to 1,200 bn USD, polarized around mature markets, with growth coming from generic products and oncology



3 Generics market is characterized by a fragmented competitor landscape, diverse product mix, and growth coming from emerging markets



~30%
average EBITDA margin for global pharmaceutical labs (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%

~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

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

B Overview and trends of the African pharmaceutical market

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



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



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



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



| | | | | |
|--|--------------|--|--------------|--|
| <p>~25 \$</p> <p>pharmaceutical spend per capita, 6 times lower than the world average of ~160 USD per capita</p> | <p>&</p> | <p>~40%</p> <p>of total sales concentrated in Northern African countries, and Eastern and Western Africa driving the 5.2% future growth until 2024</p> | <p>&</p> | <p>Top 10</p> <p>Countries representing ~75% of the total market</p> |
| <p>+3.1%</p> <p>growth rate of generic products, supporting the African market expansion</p> | <p>&</p> | <p>~40%</p> <p>of the total sales are generic products, lower than in generics-driven markets like China and India (~70%)</p> | <p>&</p> | |
| <p>2</p> <p>innovative type of products (biosimilars and oncology) are the fastest growing technologies in terms of demand in Africa</p> | <p>&</p> | <p>~6%</p> <p>growth rate of biosimilar products during the last 4 years, while representing ~10% of the market sales</p> | <p>&</p> | <p>~5</p> <p>companies in Africa, are currently producing biosimilar products</p> |
| <p>~50%</p> <p>of Africa's disease burden polarized around communicable disease (e.g., HIV/AIDS, respiratory infections and tuberculosis)</p> | <p>&</p> | <p>By 2030,</p> <p>non-communicable diseases are expected to represent ~45% of the continent's disease burden, a clear shift in the continent epidemiological profile</p> | | |

C 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



2 African companies show a low level of integration along the value chain, with limited to no R&D and API production capacities



3 The local production capacities focus mainly on simple manufacturing processes, generics and demand-driven therapeutic areas



4 Several barriers decrease local pharmaceuticals manufacturers' competitiveness and prevent the development of new actors



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

~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

manufacturers producing APIs are operating in Africa, compared with ~400 in India and China

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

6

main barriers hinder local manufacturers, including the lack of supportive policies, protection or preferential access to markets, regulatory approval and pricing



7

of these companies have achieved WHO pre-qualification status, illustrating the **difficulties African manufacturers face in achieving high quality standards**

7 strategic orientations arose from a comprehensive diagnostic and informed the thinking around the development of the pharmaceutical industry in Africa



Potential to further develop the African Pharmaceutical Industry...



... under certain conditions

1

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

Strategic orientations

Strategy pillars and enablers



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



Enable regional logistic integration



Help the implementation of quality industry standards



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

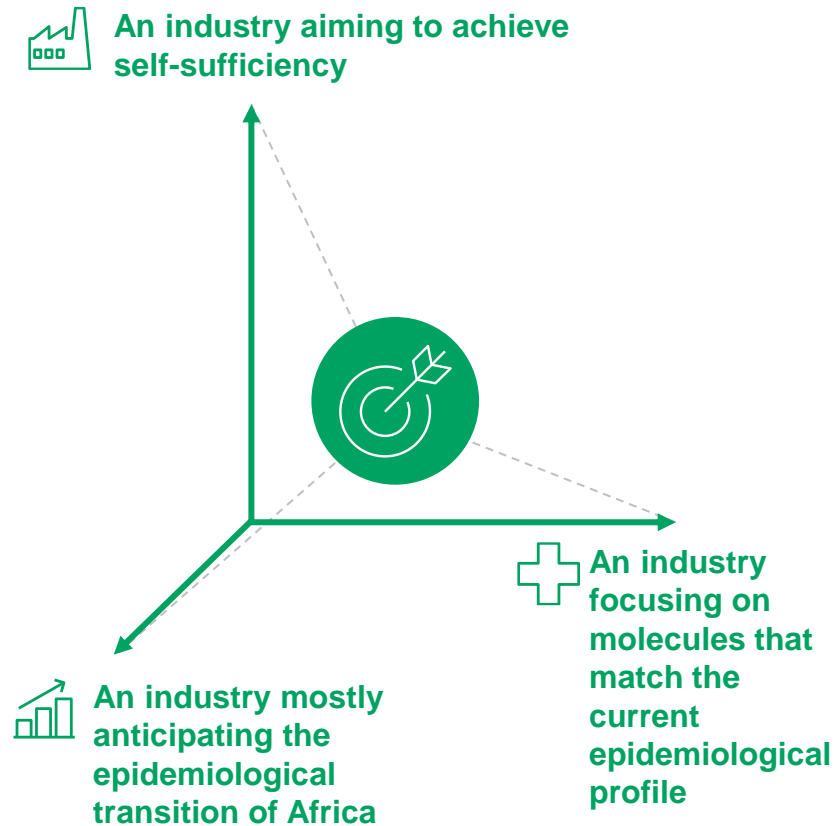


Prioritization of the investment opportunities identified based on the African Development Bank's comparative advantages



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



- 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 NCD¹**, 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

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



60-70%

Equivalent in units

~115-120 Bn

Ambition level



- **Highly ambitious target** matching the levels observed in developed countries¹ and BRICS with an increase of 30pp vs. today (~30-40%)

Achievability



Preferred path Low Medium High Very high

- **Very large investments required** from all public and private players (>USD220 Bn²)
- **Protectionist measures to be put in place**, putting at risk patients' access to medicines



45-55%

~85-90 Bn



- **Very ambitious target**, adding ~15pp vs. today's level of local production



- **Significant investments required** from both public and private sector (~USD110 Bn³)

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



30-40%

~60-65 Bn



- **Status-quo target**, in line with today's level of production (~30-40%) with basic needs not being covered



- **Low investments required** (<USD15 Bn⁴)

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

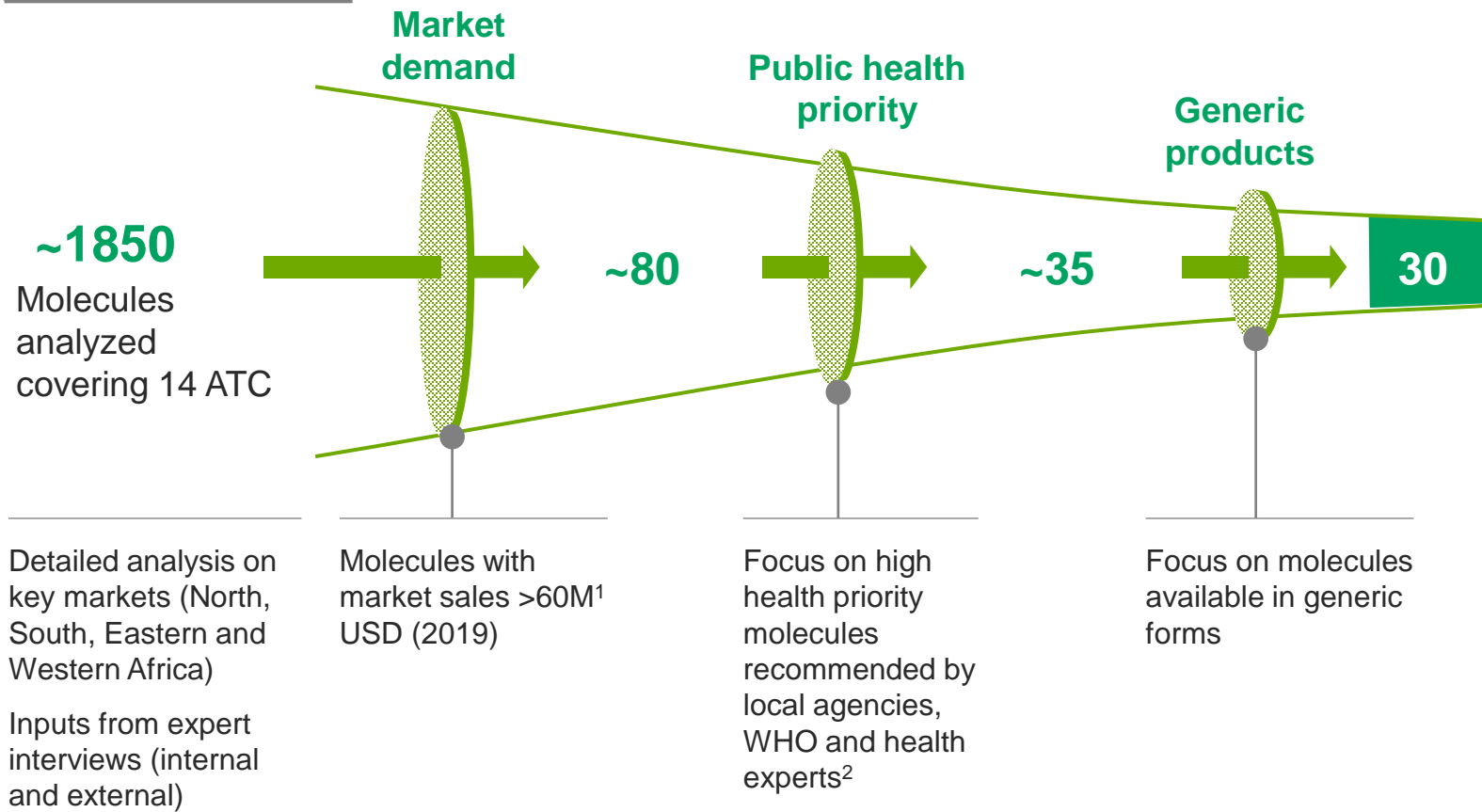
3 As detailed in the strategy

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

NON EXHAUSTIVE LIST



| Form / Technology | 2019 sales, Mn USD | Manufacturing complexity |
|------------------------|--------------------|--------------------------|
| Solid oral form | 5.692 | High |
| Biosimilars | 624 | Very High |

¹ Market sales allowing for economic viability for potential manufacturers. ~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

Value in 2019 ➔ **2030 target**



SUPPORT THE DEVELOPMENT OF SUSTAINABLE LOCAL MANUFACTURING CAPABILITIES ADDRESSING AFRICA'S PHARMACEUTICAL NEEDS



STRATEGIC PILLAR

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

30-40%

➔ **45-55%**

Share of local production in value by 2030

1. Support the development of local manufacturers on essential molecules to serve their local markets

2. Foster the expansion of African and mid-sized international companies on essential molecules within selected countries

3. Help mature pharmaceutical companies diversify their product portfolio and technologies

~8-9 Bn units



35 Bn units

Targeted production of local manufacturers

~11-13 Bn units



55 Bn units

Targeted production of mid-sized global and Af. champions

5



15

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

~USD 600 Mn



USD 1 Bn

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

~20%



50%

Of all pharma manufacturers adhering to GMP¹ standards



ENABLER III

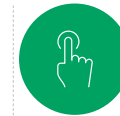
Seed the creation of R&D capacities focusing on Africa specific diseases and needs

~USD 1.5 Bn



USD 2.4 Bn

Pharmaceutical R&D investment in the continent by 2030, i.e. **+~50%**



ENABLER IV

Pave the way for increased vaccines manufacturing on the continent

<1% of local production



5 Plants

Continent platforms supplying a significant share of the needs

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



Support the development of local manufacturers on to serve their local markets



Foster the expansion of African and mid-sized international companies on essential molecules within selected countries



Help mature pharmaceutical companies diversify their product portfolio & technologies

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**



Strategic axis KPIs

Local manufacturers current production sites capacity upscaling

New production lines capacity of local manufacturers

Upscaling of current production capacity operated by mid-sized International companies and transnational champions

Creation of new production lines operated by mid-sized international companies and transnational champions

Number of African manufacturers producing biosimilars

Africa biosimilar production capacity

| | Baseline | Aspiration levels | |
|--|---------------|-------------------|--------------|
| | 2020 | 2025 | 2030 |
| Local manufacturers current production sites capacity upscaling | ~8.5 Bn units | ~13 Bn units | ~19 Bn units |
| New production lines capacity of local manufacturers | N.A | ~7 Bn units | ~16 Bn units |
| Upscaling of current production capacity operated by mid-sized International companies and transnational champions | ~14 Bn units | ~16 Bn units | ~20 Bn units |
| Creation of new production lines operated by mid-sized international companies and transnational champions | N.A | ~15 Bn units | ~35 Bn units |
| Number of African manufacturers producing biosimilars | 5 | 10 | 15 |
| Africa biosimilar production capacity | ~25 Mn units | ~40 Mn units | ~70 Mn units |

With fragmented trade and inconsistent logistics/freight capacities in Africa, defining 4 pharmaceutical hubs could enable to facilitate pharma trade integration



★ Top nerve centers candidates based on manufacturing and logistics potential ■ Potential nerve centers ■ Potential hub members

1 West Africa



2 South Africa



3 East Africa



4 North Africa



The definition of the hubs is meant to evolve depending on countries' economic evolutions and governments' policies

Potential nerve centers

- Côte d'Ivoire ★
- Ghana ★
- Nigeria ★
- Senegal ★
- Mauritius ★
- South Africa ★
- Zambia ★
- Ethiopia ★
- Egypt ★
- Kenya ★
- Rwanda ★
- Tanzania ★
- Uganda ★
- Morocco
- Tunisia
- Algeria

Potential hub members

- Benin
- Burkina Faso
- Cameroon
- Cabo Verde
- Central Af. Rep.
- Chad
- Gabon
- Gambia
- Guinea
- Guinea-Bissau
- Liberia
- Mali
- Niger
- Sierra Leone
- Togo
- Angola
- Botswana
- Comoros
- Congo
- Eswatini
- Lesotho
- Madagascar
- Malawi
- Mozambique
- Namibia
- Zimbabwe
- Burundi
- Comoros
- Djibouti
- Eritrea
- Seychelles
- Somalia
- South Sudan
- Sudan
- Mauritania
- Libya

Cameroun, Gabon, C. Af. Rep., Congo and DRC were included in West Af. And South Af. as there is no potential nerve center in Central Af.

The North African hub will have a different purpose, mostly aiming at exporting to the entire continent (*detailed next*)

1. Economic Community of West African States | 2. West African Economic and Monetary Union | 3. Common Market for Eastern and Southern Africa | 4. Southern African Development Community | 5. East African Community

Source: Expert interviews

The fragmented trade integration of the continent and the inconsistent logistic capacities underline the need to have a regional perspective at pharmaceutical trade

4 pharmaceutical hubs were identified based on regional proximity and Regional Economic Communities

In each hub, potential nerve centers were identified. These are countries with developed or potential pharma industry

In order to supply their region, nerve centers should be well connected and integrated into their hub

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

A Foster pharmaceutical trade integration over the continent



B Create regional hubs with logistics capacities enabling exports



C Support the development of local distributors



Description

Accelerate the **intra-regional and intra-continental trade integration** through **deeper regional collaboration** and **ratification of a continental-wide trade agreement**

Create regional hubs and **identify their potential nerve centers**

Select key projects to foster **through technical or financial support**

Develop **logistic infrastructures and connections** for the different regional hubs

Support the **development of local distributors** to enable the emergence of a **balanced competitive landscape in the key markets**

Foster the **development of regional⁶ distributors** able to **serve regional hubs**



Strategic axis KPIs

UNECA average trade integration index of **the 11 top potential nerve centers**

Continental average World Bank **logistics index**

Number of **African regional/continental distributors**

Number of **local distributors** among top 10 of their country

| | Baseline | Aspiration levels | |
|---|------------------|-------------------|-------------------|
| | 2020 | 2025 | 2030 |
| UNECA average trade integration index of the 11 top potential nerve centers | 0.41 | 0.51 | 0.63 ¹ |
| Continental average World Bank logistics index | 2.5 ² | 2.75 | 3.0 ³ |
| Number of African regional/continental distributors | 0 | 1 | 4 ⁴ |
| Number of local distributors among top 10 of their country | 20 ⁵ | 35 | 50 |

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 GMP¹ standards per region

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 **GXP¹ standards** for all players

Strengthen NMRA capabilities by building capabilities of their personnel and implementing comprehensive QMS³ to ensure adequate inspections and assessments

Enhance market integration through drug regulatory harmonization and regulatory policy alignment at regional then continental level

Higher standards and strengthened NMRAs could enable to **diminish the counterfeit market**



Strategic axis KPIs

Density of pharmacists per 10,000 people

Number of pharmaceutical industry education programs

Number of pharmaceutical manufacturers adhering to national or regional GMP¹ norms

Number of regions² with harmonized medicines registration regulatory standards

Number of continental medicine regulatory authority

| | Baseline | Aspiration levels | |
|--|----------|-------------------|------|
| | 2020 | 2025 | 2030 |

| | | | |
|--|---|---|---|
| Density of pharmacists per 10,000 people | 1 | 3 | 6 |
|--|---|---|---|

| | | | |
|--|-----|-----|-----|
| Number of pharmaceutical industry education programs | 130 | 200 | 300 |
|--|-----|-----|-----|

| | | | |
|--|-----|-----|-----|
| Number of pharmaceutical manufacturers adhering to national or regional GMP ¹ norms | 100 | 150 | 300 |
|--|-----|-----|-----|

| | | | |
|--|---|---|---|
| Number of regions ² with harmonized medicines registration regulatory standards | 0 | 2 | 4 |
|--|---|---|---|

| | | | |
|---|---|---|---|
| Number of continental medicine regulatory authority | 0 | 0 | 1 |
|---|---|---|---|

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

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**



Ambition

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

Strategic axis

A Support the development of an ecosystem to foster Research innovation



B Identify healthcare infrastructure required to support drug development (e.g., clinical trial)



Description

Help the African pharmaceutical industry **develop Research activities** by:

- Supporting the development of a **favorable research ecosystem** via collaborations between pharmaceutical companies and universities research centers
- Investing in **Biotech startups**
- Developing strong **partnerships** between **MNCs and African pharma companies** to reinforce capacities

Boost the **improvement of Phase 1 to 4 clinical trials** by:

- Establishing a **strong clinical trials infrastructure** base in Africa
- Incentivizing **pharmaceutical service providers** to **conduct operations** in the continent

Synergies may exist between the Healthcare Infrastructure Strategy and Enabler III



Strategic axis KPIs

Aspiration levels

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

Executive Summary – Intervention model of the AfDB for vaccines manufacturing

1 The context of the vaccines industry – Why now?

- **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)

2 Vaccines supply and demand balance

A Overview of the demand

- 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**

B Overview of the supply

- **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

3 Strategic move for AfDB

A Estimates of the needs in manufacturing capacities by 2040

- 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

B Options for the intervention of the AfDB

- **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 ants and to create a guarantee fund

~USD111 Bn investments could be required on the continent by 2030 to help the development of the pharma manufacturing capacities and required infrastructures

Pillar and enablers

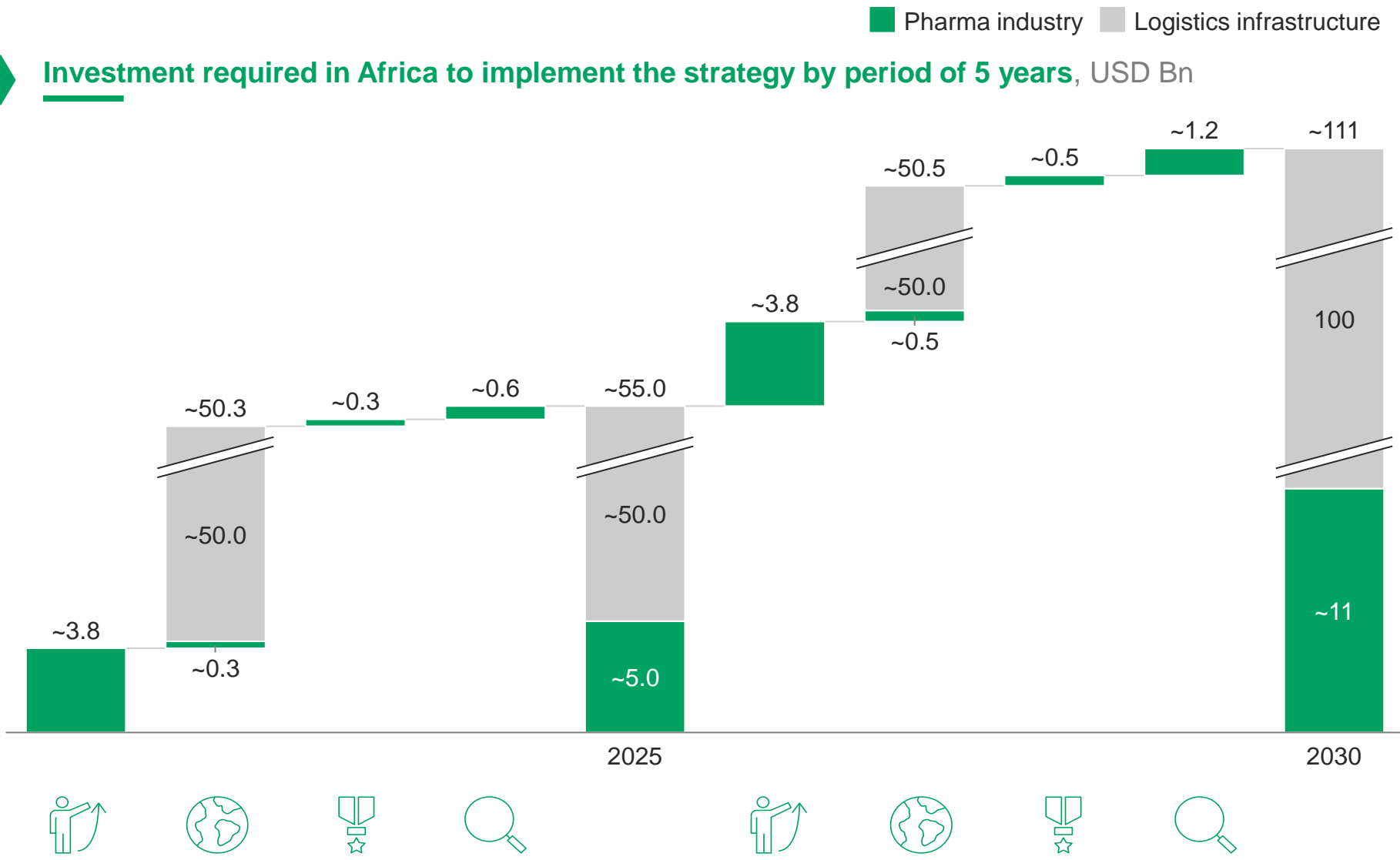
Increase the maturity of the industry by supporting the development of local production capacities

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

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



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

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

XX Avg. share of AfDB investment on the total investment required

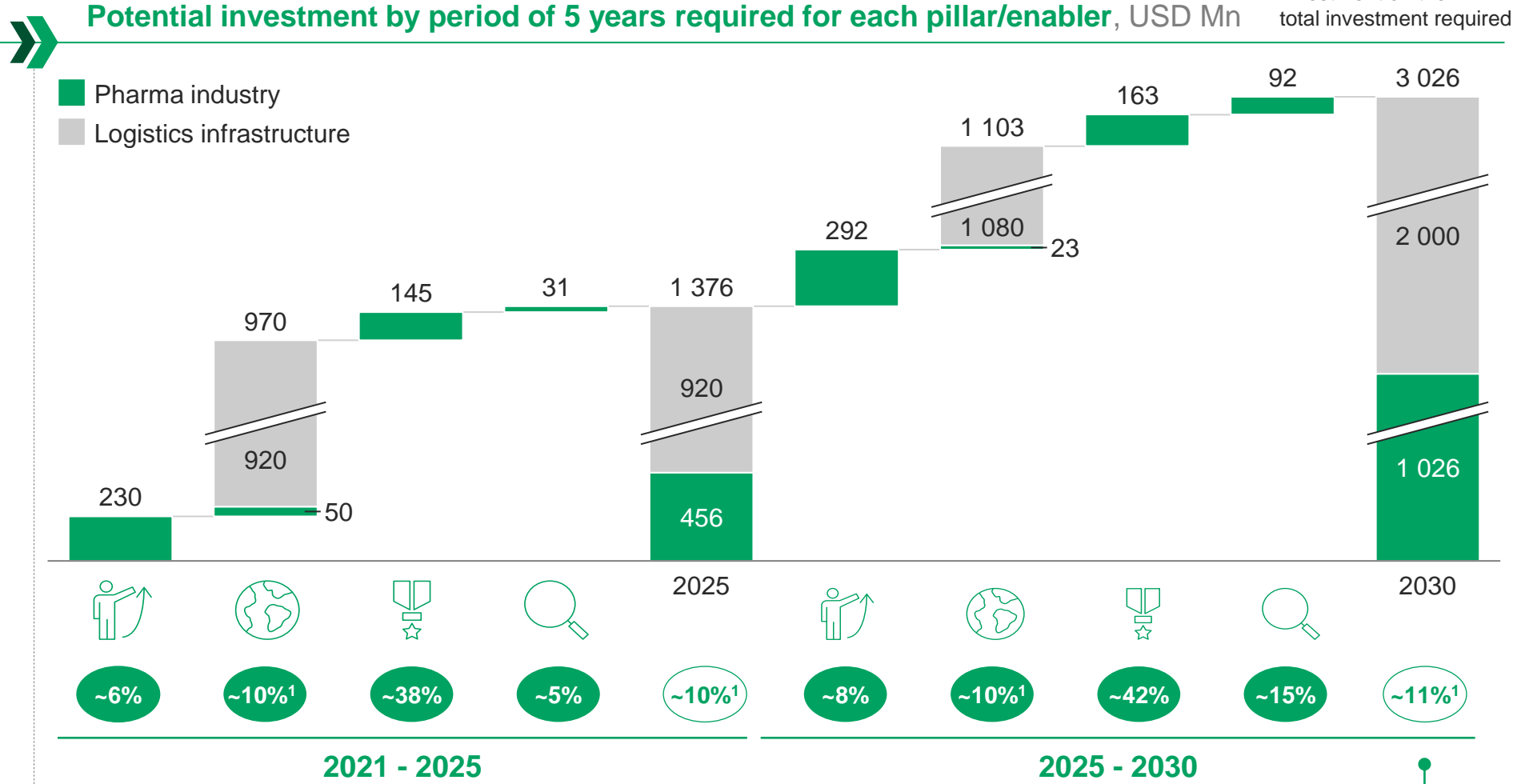
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~USD 2 Bn investment on logistics infrastructure that will benefit economic sectors beyond pharma

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