



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

AfDB

Presentation to PITD, March 2023



Agenda

Context, Rationale and Objectives of Bank's Pharmaceutical Industry Study

Findings from Diagnostic Study

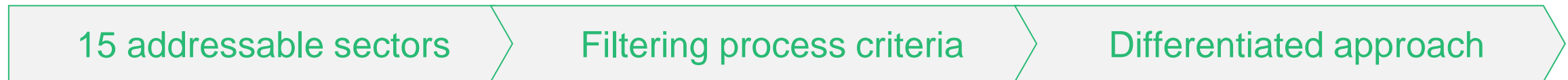
Pharmaceutical Vision for Africa

Vaccine Manufacturing

AfDB's Resources and Implementation

Prioritization: Industrial sectors with highest impact

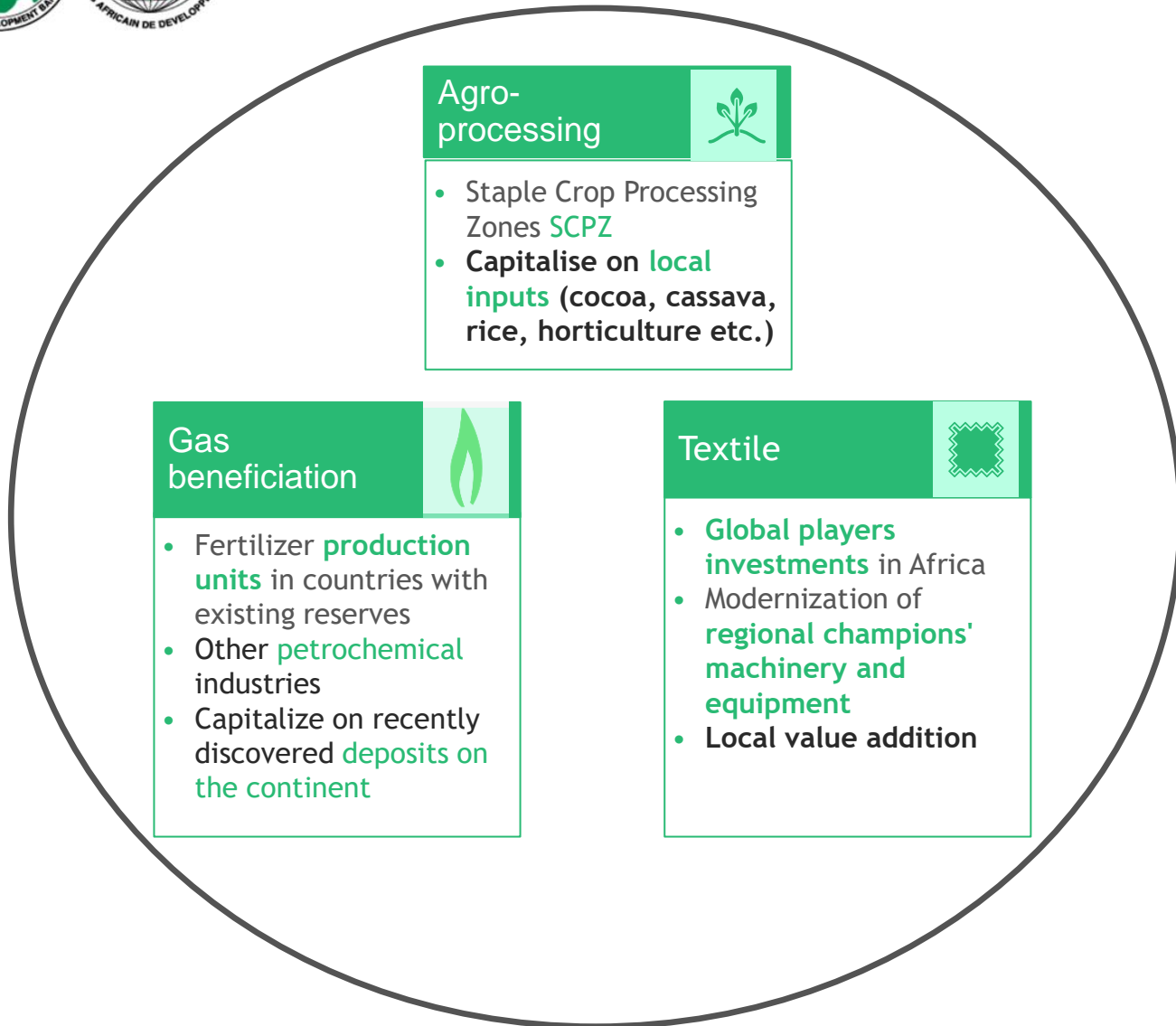
Differentiated approach with 3 tiers (2018)



| 15 addressable sectors | | | Filtering process criteria | Differentiated approach |
|------------------------|-------------------------|----------------------------|--|--|
| ICT ★ | Building materials | Hospitality | <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> |
| Fertilizers | Transport and logistics | Consumer Goods | | <p>2 "Tier 2" sectors: proactive monitoring</p> <ul style="list-style-type: none"> Sector analysis <u>To monitor</u> |
| Mining | Textile | Retail | | <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> |
| Pharmaceuticals ★ | Automotive | Machinery & Equipment | | |
| Metals manufacturing | Consumer Durables | Chemicals & Petrochemicals | | |

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

The New Paradigm (2020 and beyond)



Agro-processing

- Staple Crop Processing Zones **SCPZ**
- Capitalise on **local inputs** (cocoa, cassava, rice, horticulture etc.)

Gas beneficiation

- Fertilizer **production units** in countries with existing reserves
- Other **petrochemical** industries
- Capitalize on recently discovered **deposits on the continent**

Textile

- **Global players investments** in Africa
- Modernization of **regional champions' machinery and equipment**
- **Local value addition**

ICT

- Large **connectivity infra** projects (telco, towers, datacenters, etc.)
- **Large ICT players** (telco, e-commerce, apps and services, etc.)

Pharmaceuticals

- MNC & African champions **manufacturing capacity increase**,
- **Meet international standards (GMP)**
- Avail **local supply**.

Enabling the digital revolution and financial inclusion

Local supplies and healthcare resilience

Value addition to natural resources



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



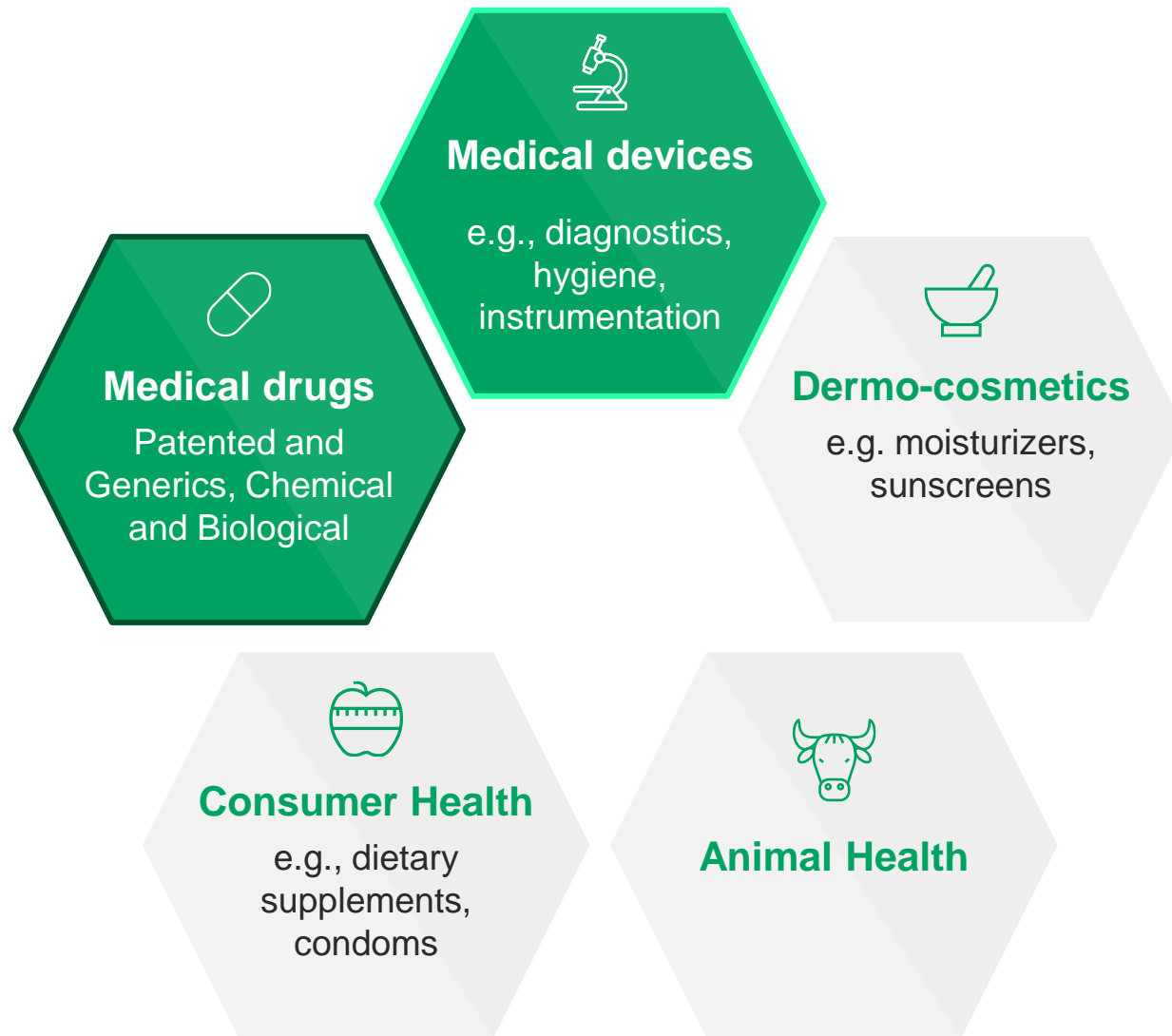
- **Defining the ambition** for Africa's local pharmaceutical production
- **Clarifying the Bank's vision and approach** for the pharmaceutical sector by 2030 and identifying a toolkit for the Bank to use to support the development of the sector (e.g., modes of intervention, financing instruments), including 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.

The strategy focused on medical drugs and vaccines among the 5 that compose the pharmaceutical industry; medical devices is covered separately



-  Focus of the diagnostic
-  Focus of the Strategy Steering Committee
-  Next step



Diagnostic performed on **the medical drugs and medical devices markets**. The **steering committee will focus on the medical drugs market** showing the higher potential for local production in Africa

The Core Team for the pharma strategy preparation gathered a diversity of stakeholders from AfDB into a Leadership Committee, a Steering Committee and a Technical Team

| | <u>Role</u> | <u>Name</u> | <u>Position</u> |
|---------------------------------|--|-------------------------------|--|
| Leadership Committee | Sponsors the project and validates the strategy | Mr. Solomon Quaynor | VP Private Sector, Infrastructure & Industrialization |
| | | Dr. Khaled Sherif | VP Regional Development, Integration and Business Delivery |
| | | Dr. Rabah Arezki | VP Economic Governance and Knowledge Management |
| | | Pr. Banji Oyelaran-Oyeyinka | Chief of staff, Director of Cabinet of the President, Special advisor on industrialization |
| | | Mr. Mohamed El Azizi | Director General, North Af. regional development and Business delivery office |
| | | Dr. Josephine Waithira Ngure | Country Manager Southern Af. Regional Development and Business Delivery Office |
| | | Ms. Nnenna Nwabuo | Country Manager, East Af. Regional Development and Business Delivery Office |
| | | Ms. Marie Laure Akin-Olugbade | Country Manager, West Af. Regional Development and Business Delivery Office |
| | | Mr. Ebrima Faal | Former Senior Director, Nigeria |
| | | Ms. Victoria Chisala | Director of the Policy and Strategy Department's on Non-Sovereign Operations policy |
| | | Ms. Martha Phiri | Senior Director, Rwanda |
| | | Ms. Moono Mupotola | Director, NEPAD, Regional Integration & Trade Department |
| | | Dr. Emmanuel Pinto Moreira | Director, Country Economics Department |
| | | Ms. Karen Rot-Münstermann | Acting Evaluator General for the Independent Evaluation Development Department |
| Steering Committee | Shares insights on the strategy and enlightens critical decisions | Dr. Abdu Mukhtar | Director, PITD |
| | | Mr. Thomas Viot | Chief Coordinator Industrialization |
| | | Ms. Dorsaf Zangar | Division Manager Industrial Development |
| | | Mr. Nicholas Williams | Head of ICT division |
| | | Mr. Alhassane Haidara | Division Manager Non Sovereign Operations Industries & Services |
| | | Mr. Andoh Mensah | Principal Country Program Officer |
| Technical Team | Leads the strategy preparation on a day-to-day basis | Dr. Ghada Abuzaid | Program Coordinator |
| | | Mr. Fernando Rodrigues | Chief Investment Officer PITD |
| | | Dr. Dauda Suma Foday | Principal Industrial Development Officer |
| | | Ms. Sauda Mukhtar | Consultant |

The Pharma Strategy benefited from insights and feedbacks of all stakeholders

After conducting nearly 55 interviews and consulting 30 reports for the diagnostic phase, a second round of interviews took place for the strategy phase

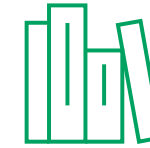


We interviewed around 40 different stakeholders in the pharmaceutical industry

15+ interviews with pharmaceutical company executives and PE fund managers (e.g., Pfizer, GSK, Actis)

~25 interviews with African Development Bank staff

15+ interviews with national and international experts from the pharmaceutical sector



We consulted more than 30 reports and databases

30+ reports published by local private players, presenting the pharmaceutical industry's current situation and potential

~10 reports published by international institutions on the pharmaceutical sector in Africa

~5 international databases focusing on the pharmaceutical sector

hikma.

COOPER PHARMA

AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

IDB Inter-American Development Bank

ADB ASIAN DEVELOPMENT BANK

S&P CAPITAL IQ
McGRAW HILL FINANCIAL

International Trade Centre

Evaluate

gsk
GlaxoSmithKline

TERIAK
Laboratoires

Pfizer



IDA

eurostat

UNcomtrade

IQVIA

WORLD BANK GROUP

FitchSolutions

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

1 Very different levels of profitability exist between pharma labs and generic manufacturers driven by R&D and production dynamics



Production cost

API

FDF

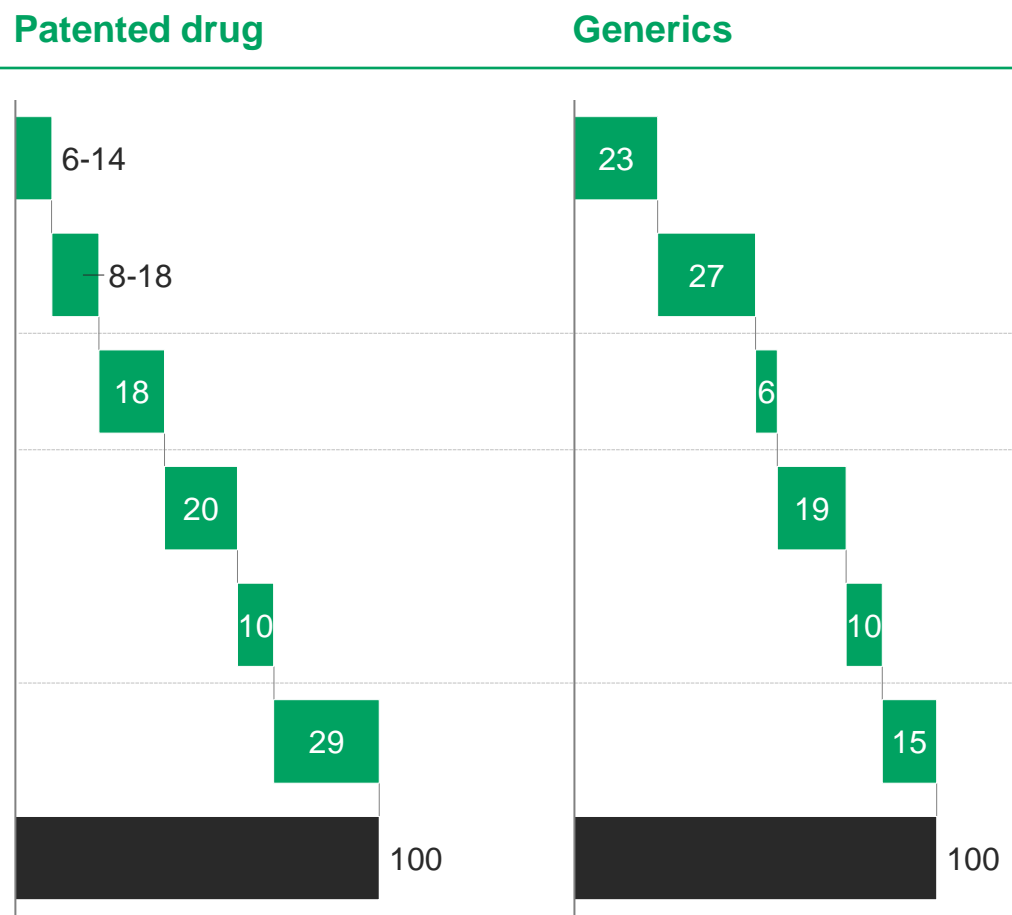
R&D

Marketing & Sales

SG&A¹

EBIT

Revenue



Rationale

For generics, COGSs represent ~50% of total production cost

Generic companies, which are not focused on innovation, require much less R&D investment

On a per-dollar basis, originator and generic companies spend a similar proportion on SG&A costs

Lower profitability in generics reflecting competitive market dynamics

Variable level of profitability depending on size and product portfolio

With limited ability to set prices due to the competitive market and lack of product differentiation, generic manufacturers have to compete on manufacturing and supply costs

¹ Selling, General & Administrative expenses

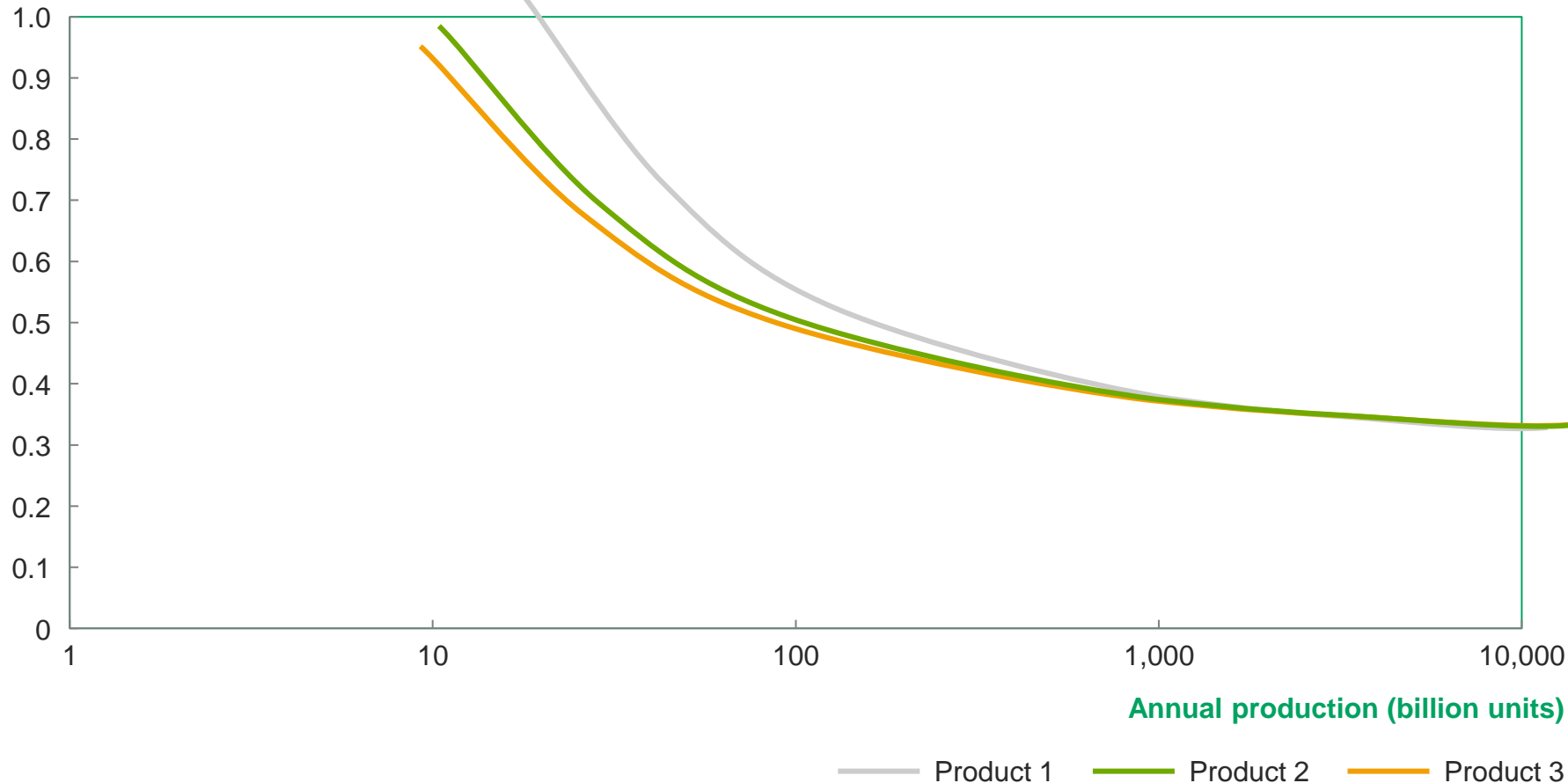
1 The pharmaceutical market is a scale market requiring sufficient target volumes to ensure the cost competitiveness of each producer



Cost based on factory production in a country X, Billions of tablets¹

Standardized cost

ILLUSTRATIVE - CONCEPTUAL



With a production of 2 billion units, a Chinese or Indian player will always be more competitive than a local player producing 10-15 million units, even taking into account the costs of transport in the region. In this market, it's all about scale!

– *International producer*

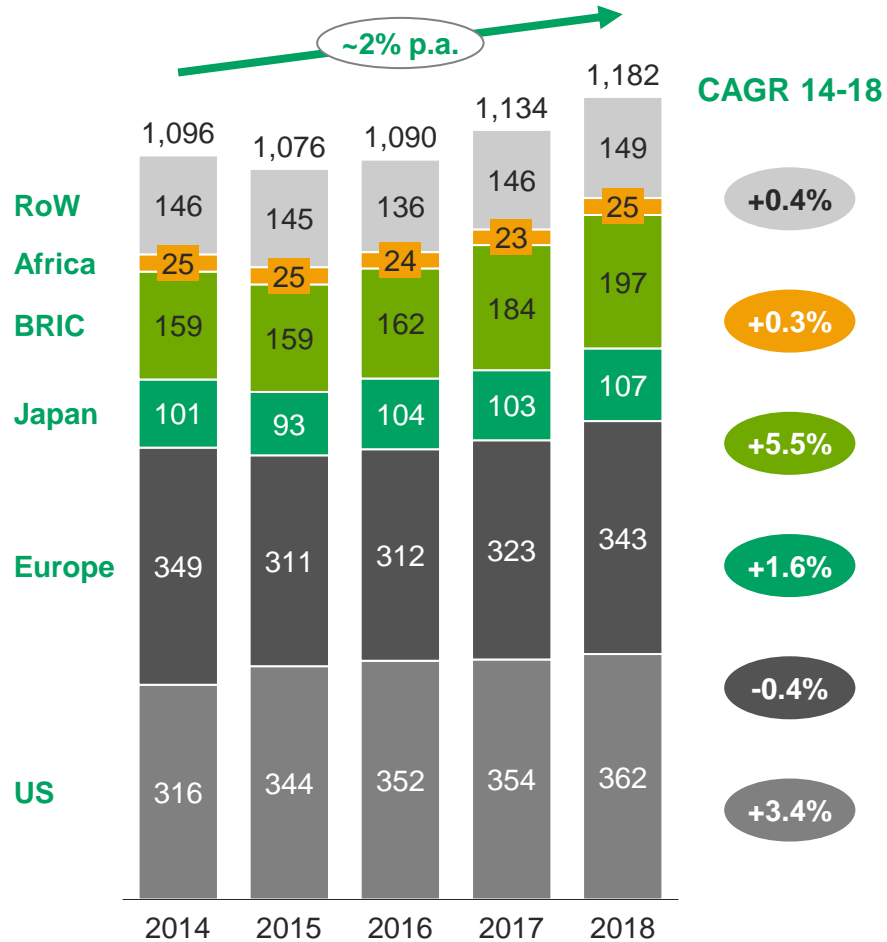
1. Assumptions that plants are completely depreciated

Source: Interviews with manufacturing players in Senegal, Europe and Jordan (conducted in June 2020)

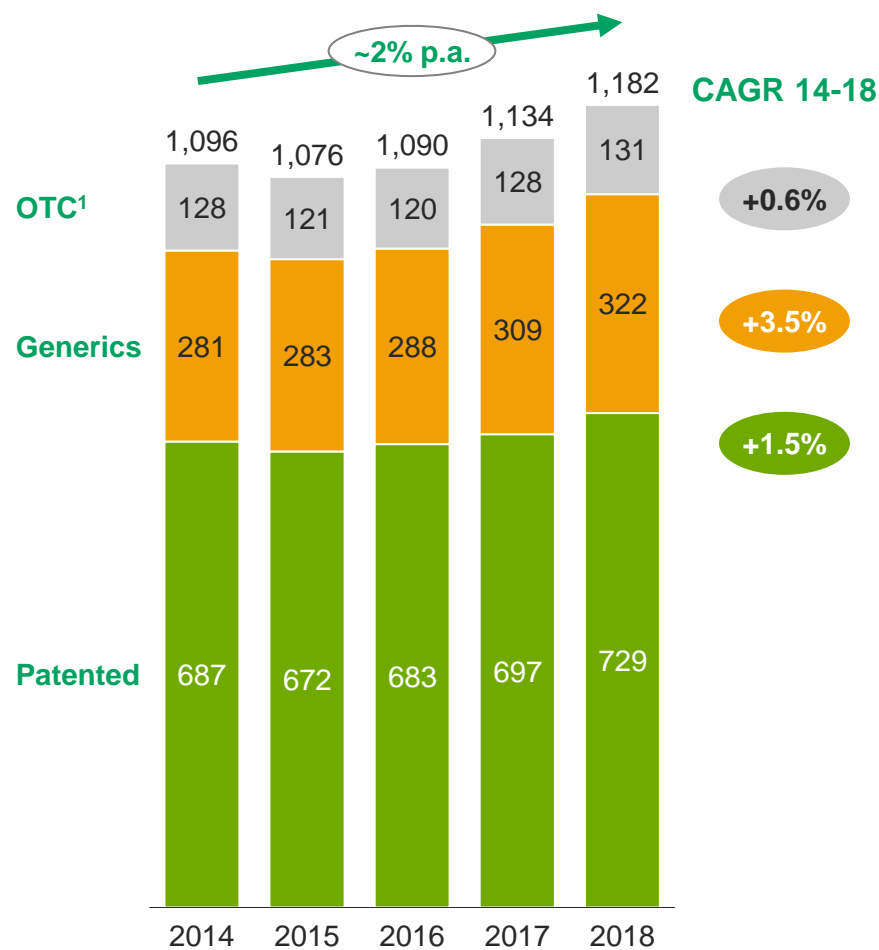
2 The pharmaceutical market is a ~1,200 Bn USD market with historical growth mainly driven by the BRIC countries and the penetration of generics



Total Pharmaceutical Sales by Geography
Bn USD



Total Pharmaceutical Sales by Product Type
Bn USD



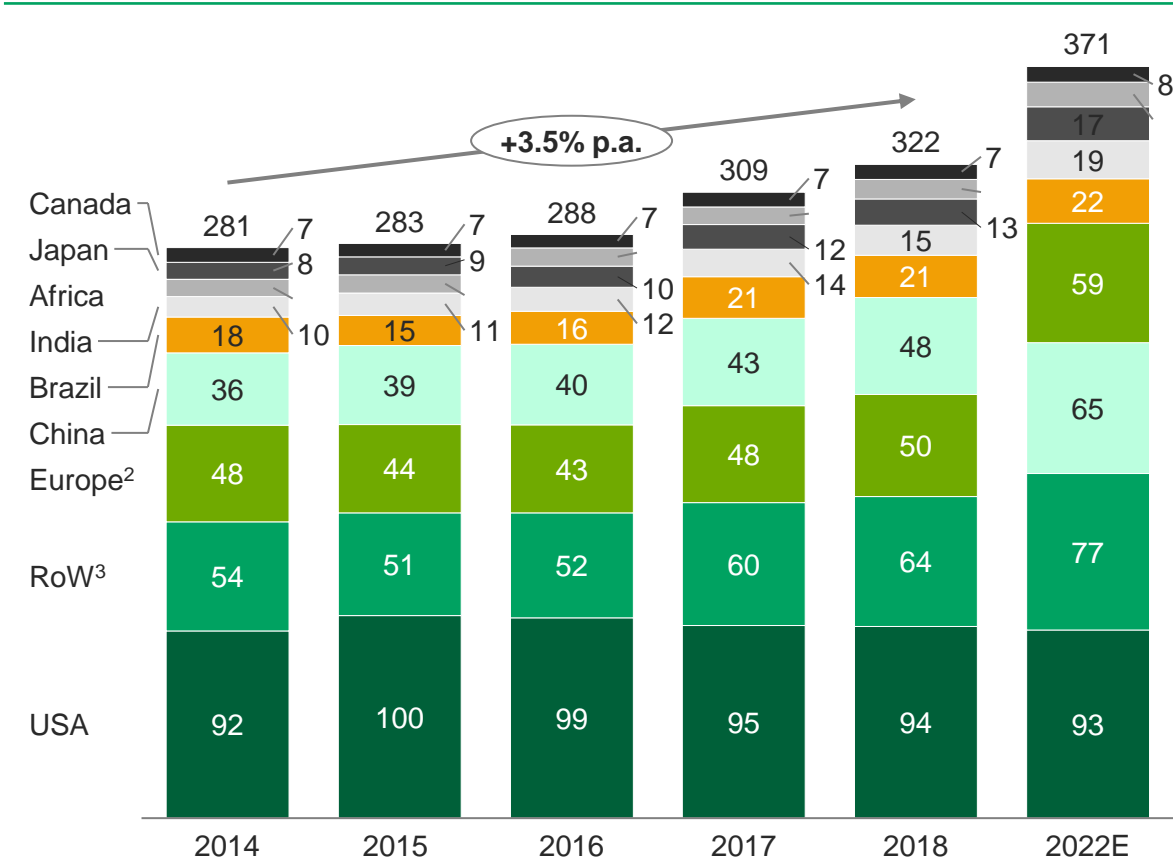
- The United States and Europe polarize the market: ~60% of the total demand while the African continent concentrates only ~2%
- Despite being a mature market the United States market grew above the market during the 5 last year and is driven by patented product
- Generics products drive the market growth with an expansion rate of 3.5%, well above above the 2% market growth

¹ Over The Counter

3 While emerging countries lead the global generics market growth, the US and Europe remain the largest markets in sales



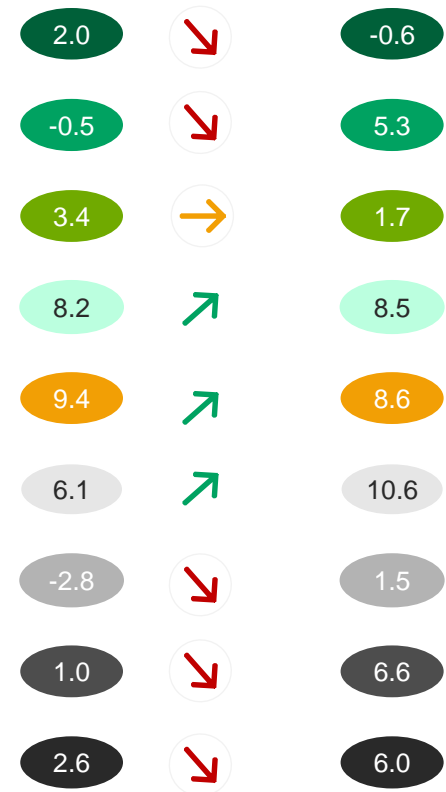
Generic small molecule net sales geographic breakdown¹; \$ billions



Growth compare to the market

↗ Higher
 → Similar
 ↘ Lower

14-18 CAGR; % 18-22 CAGR; %



- The **US and European markets** are expected to **grow** because of an **increasing number of drugs which will lose their exclusivity**, because of an increased pressure from the regulators to use generics and because of a stabilization of the prices
- There is an **increase in the share of generics in emerging markets** because of the **aging population** (mostly China and India) and because of an **improved access to healthcare**

¹ Generic drug sales, defined as the sum of revenues generated by generic drugs through hospitals, retail pharmacies and other channels. Unless otherwise stated, market value is reported at final consumer price including mark-ups, taxes, etc.

² Countries included: Germany, France, UK

³ Rest of world includes: South Korea, Italy, Russia, Spain, Argentina, Poland, Mexico, Turkey, Australia, Thailand, Pakistan, and others

B Overview and trends of the African pharmaceutical market

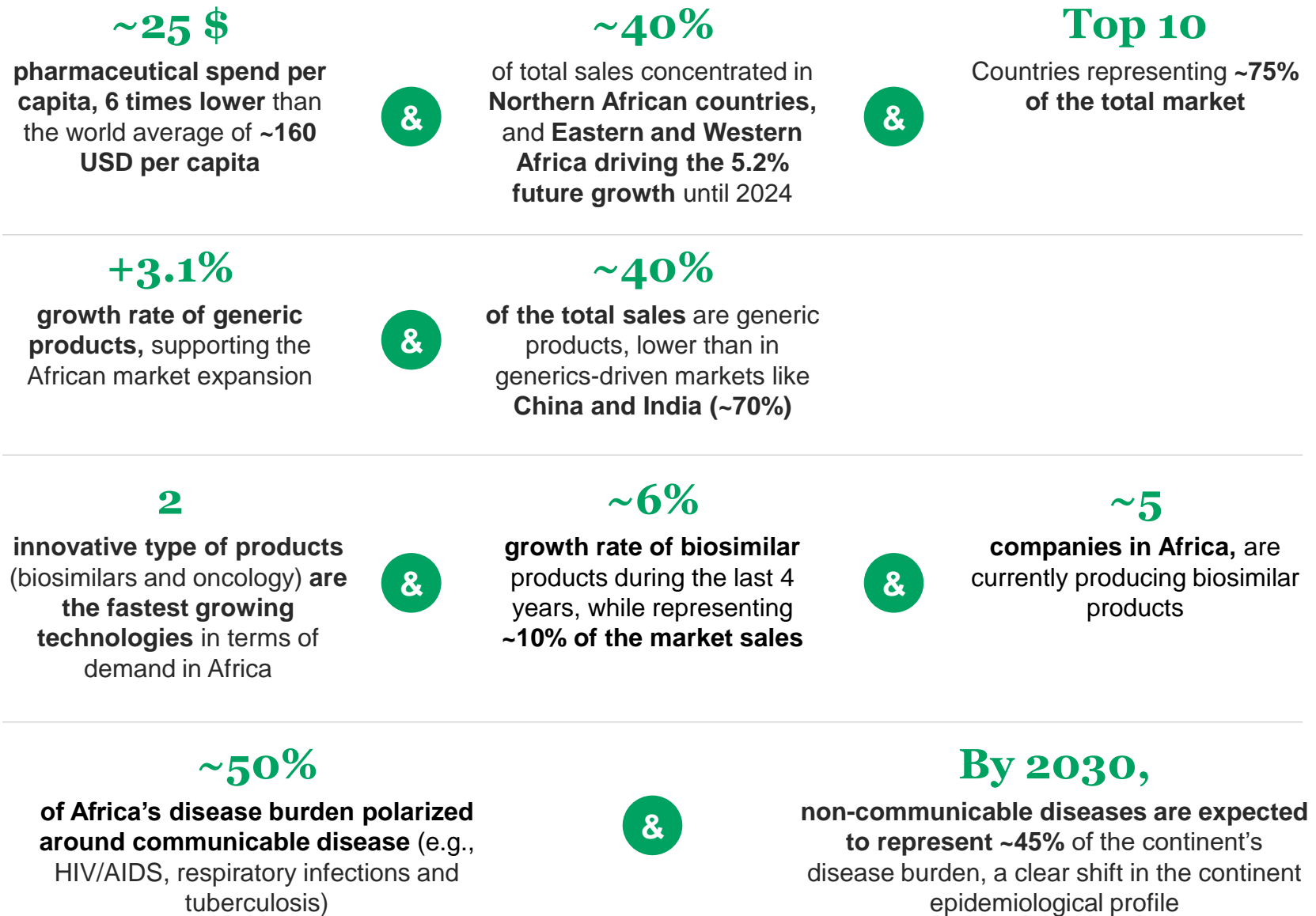
- 1** The US\$25 bn African pharmaceutical market is underpenetrated, with diverse geographic dynamics


- 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



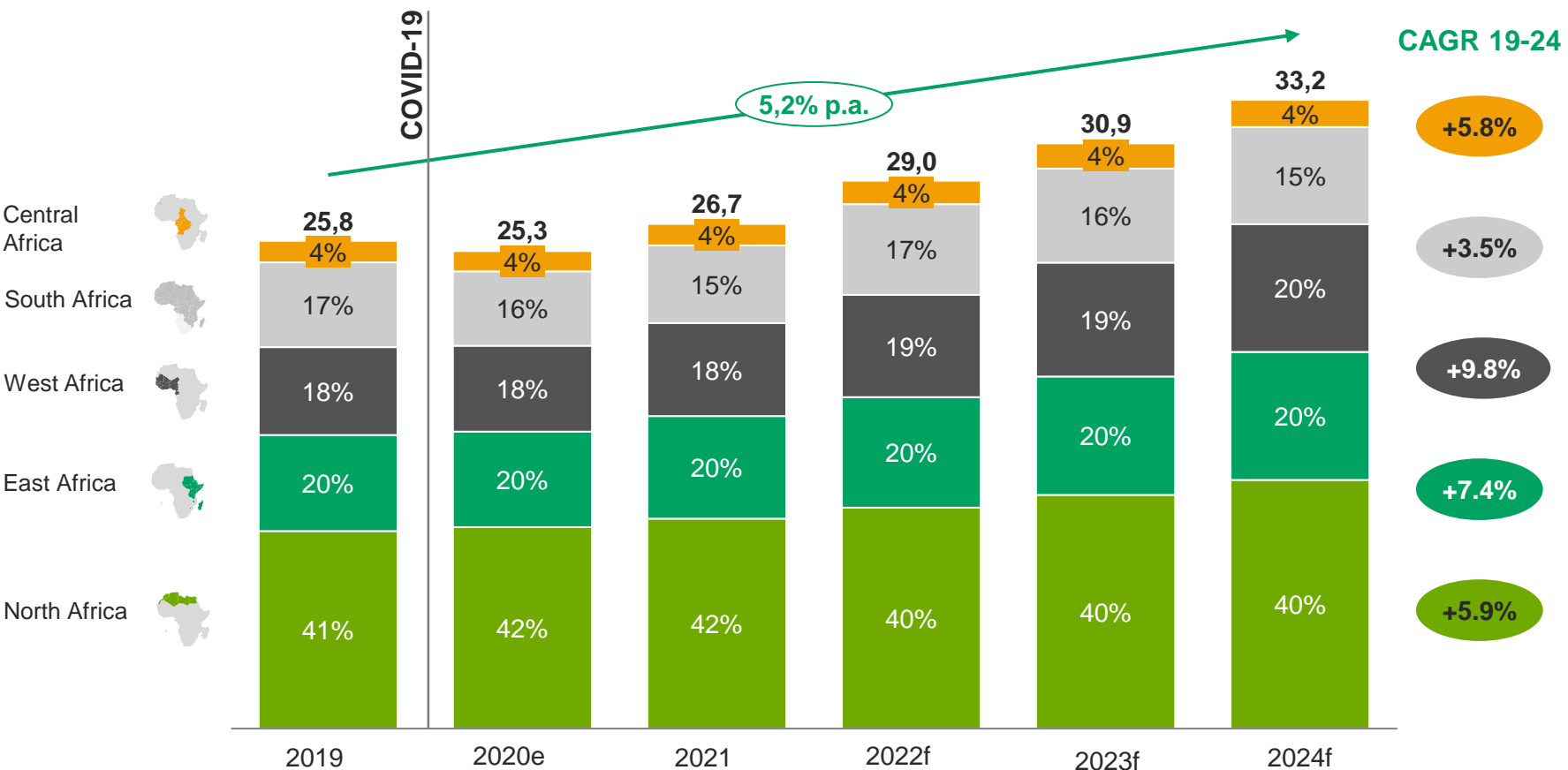


1 The African pharmaceutical market is a US\$25 bn market with an expected growth rate of ~5.2% p.a. for the next 5 years reaching US\$33 bn by 2024



Total and expected sales of pharmaceutical products per region,¹ 2019-24
Billion USD, price expressed in final purchase prices

Comments



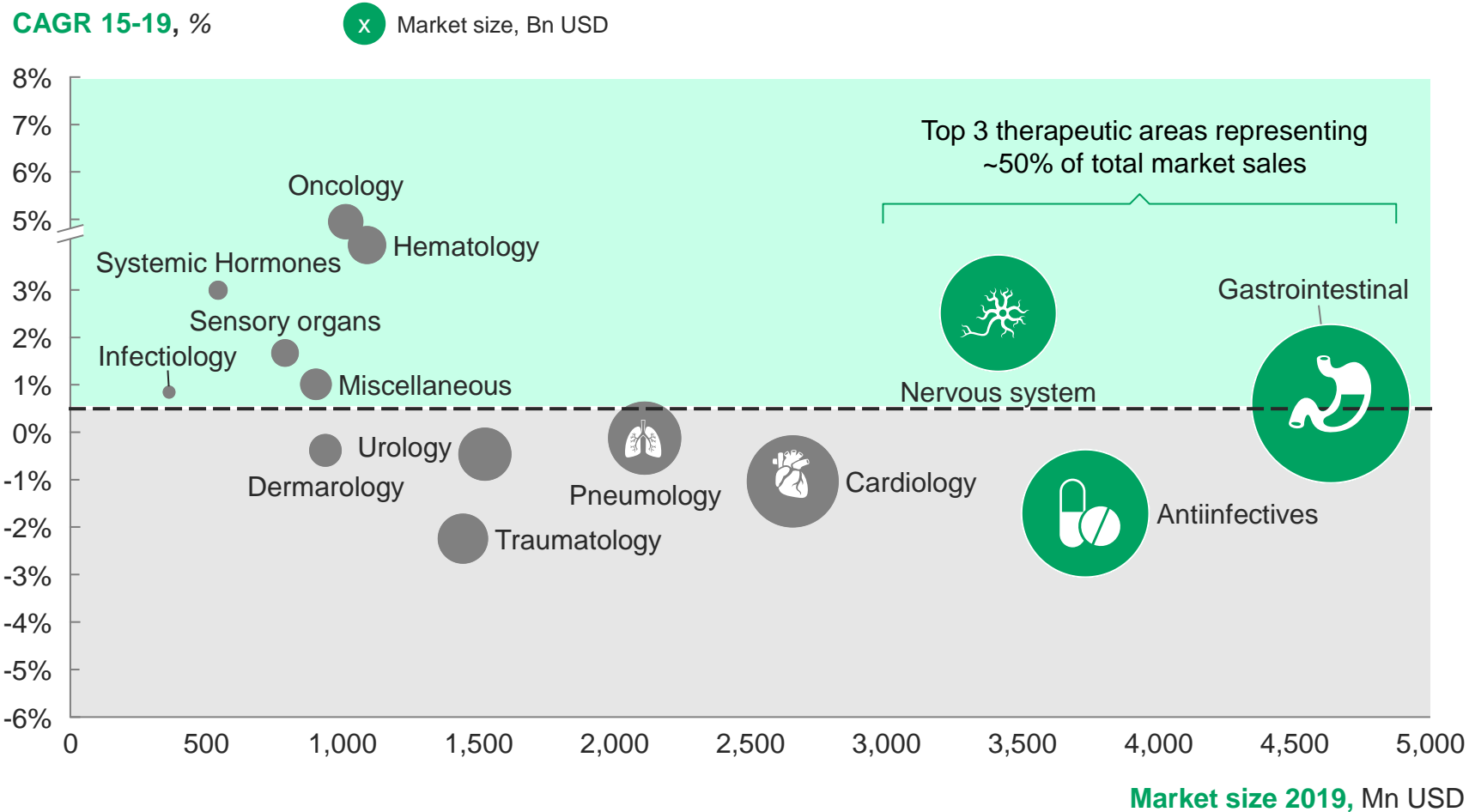
- **Northern Africa** countries concentrate ~40% of total sales driving the market in term of volumes due to an increase of **health coverage and public health expenditures** (e.g., 70% of total health expenditure are public in Algeria)
- **Eastern and Western Africa** are expected to support the **5.2% market growth**, with respective expected growth rates of **7.4% and 9.8% p.a.** explained by the increase of **medicines demand, health spent per capita** in addition to **increasing demographics**

¹ **North Africa** : Egypt, Algeria, Sudan, Morocco, Tunisia, Libya. **South Africa**: South Africa, Namibia, Botswana, Lesotho, Eswatini. **East Africa**: Ethiopia, Tanzania, Kenya, Uganda, Mozambique, Madagascar, Malawi, Zambia, Somalia, Zimbabwe, Rwanda, Burundi, S. Sudan, Eritrea, Mauritius, Djibouti, Comoros, Seychelles, **West Africa**: Nigeria, Ghana, Cote d'Ivoire, Niger, Burkina Faso, Mali, Senegal, Guinea, Benin, Togo, Sierra Leone, Liberia, Mauritania, Gambia, Guinea-Bissau, Cabo Verde, **Central Africa**: Congo (RDC), Angola, Cameroon, Chad, Congo, Central African Republic, Gabon, Equatorial Guinea

2 Three therapeutic areas, Gastrointestinal, Anti-infectives and Nervous System, represent ~50% of the overall market, with Gastrointestinal and Nervous system driving the growth



Matrix of ATC1 therapeutic areas according to their size and growth, focus on the pharmacy market



African pharmaceutical market is dominated by **3 therapeutic areas** representing **~50%** of total market sales :

- **Gastrointestinal** (e.g. Insulin, Omeprazole)
- **Anti-infectives** (e.g. Amoxicillin, Efavirenz)
- **Nervous system drugs** (e.g. Paracetamol, Codeine)

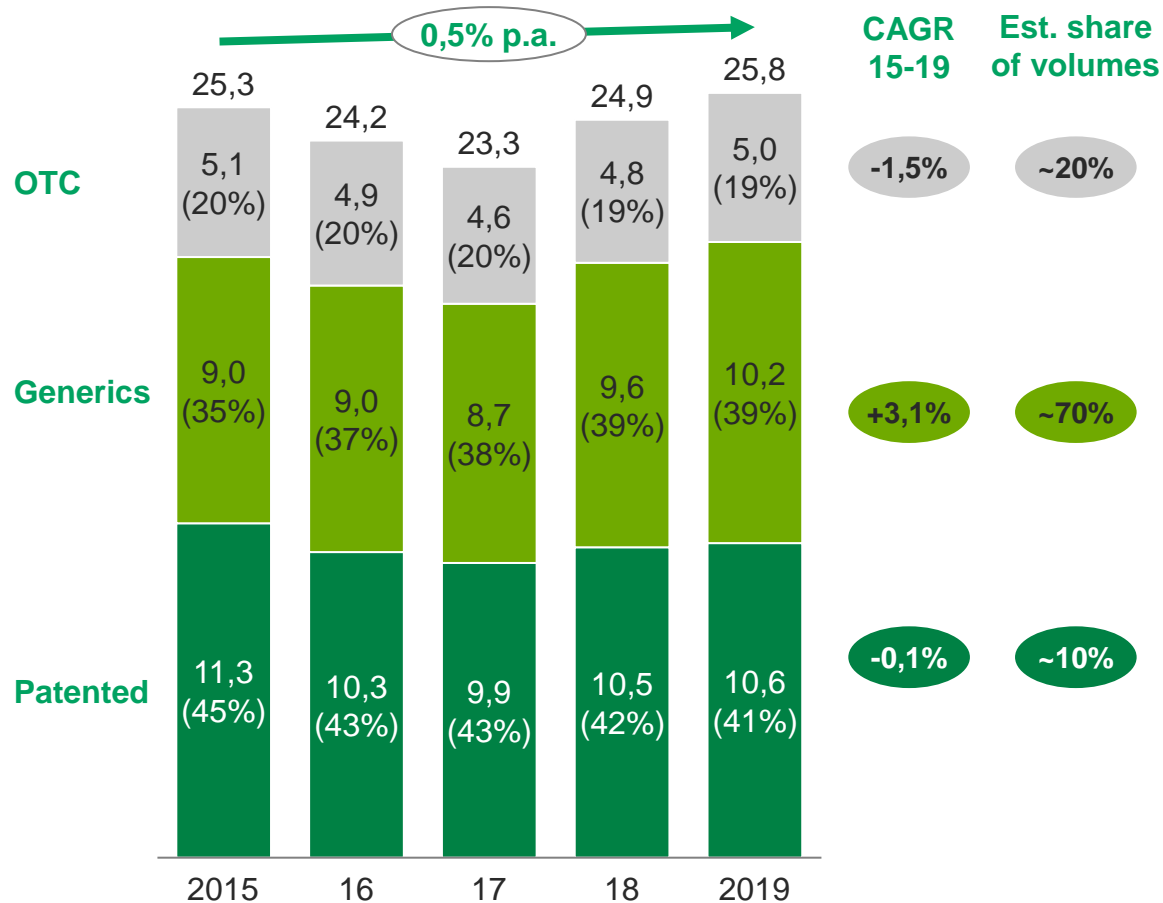
The **market growth is driven by gastrointestinal and nervous system drugs** having respective growth of **0.6%** and **2.7%** while **anti-infectives are decreasing by -1.7%**

1 Total sales including private and public markets. Public market estimated based on ATC1 private sales split. Data available for 65% of total sales, remaining countries estimated based on comparable African markets

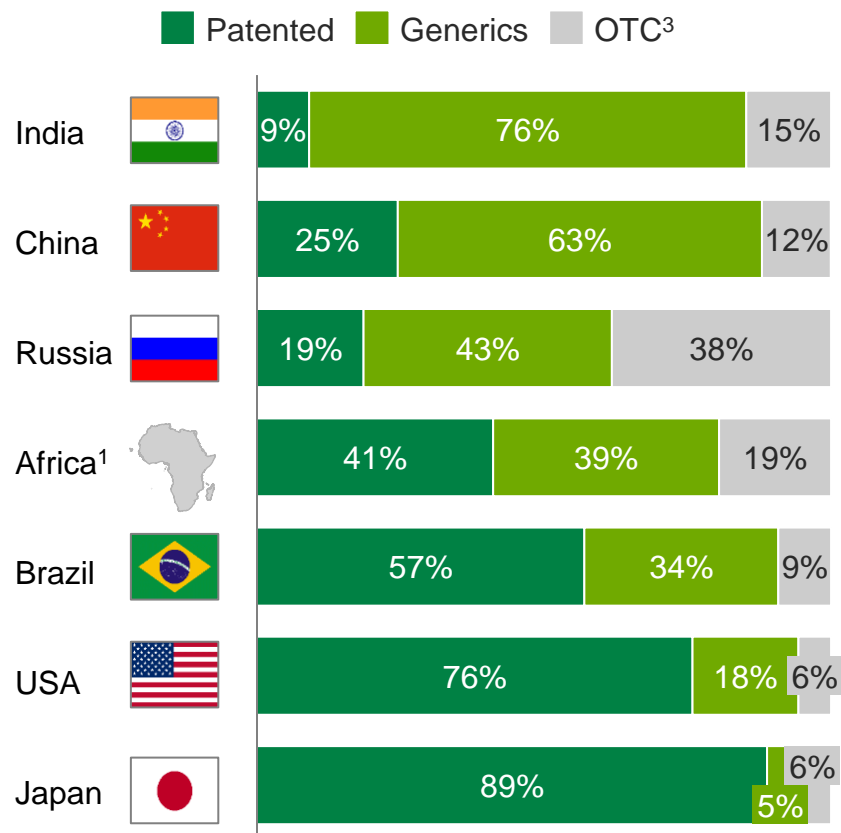
2 The growth of the African pharmaceutical market is driven by generics, which represent today ~40% of the total sales



Total African¹ pharmaceutical sales per product type²,
Billion USD



Share of total sales per product category
%, 2019



The African pharmaceutical market **growth** is driven by **generics** but remains **underpenetrated** compared to similar generics driven markets (e.g., India, China)

Generics play a central role in drug availability:

- They can be produced by new entrants in the markets
- **They are more affordable than patented drugs**

A significant share of patented products can be explained by the low confidence of **patients in generic products quality**

¹ Projected CAGRs and product split from Fitch solution only include Algeria, Egypt, Morocco, Nigeria, South Africa, Kenya, Ghana representing 65% of total sales and not the other African countries provided

² Generic drug sales, defined as the sum of revenues generated by generic drugs through hospitals, retail pharmacies and other channels.

³ Over The Counter

Source: Fitch Reports 2019

3 Biosimilars and oncology products are the fastest growing technologies requiring advanced production technologies, especially the control of biological processes






















Detailed next

 Yes

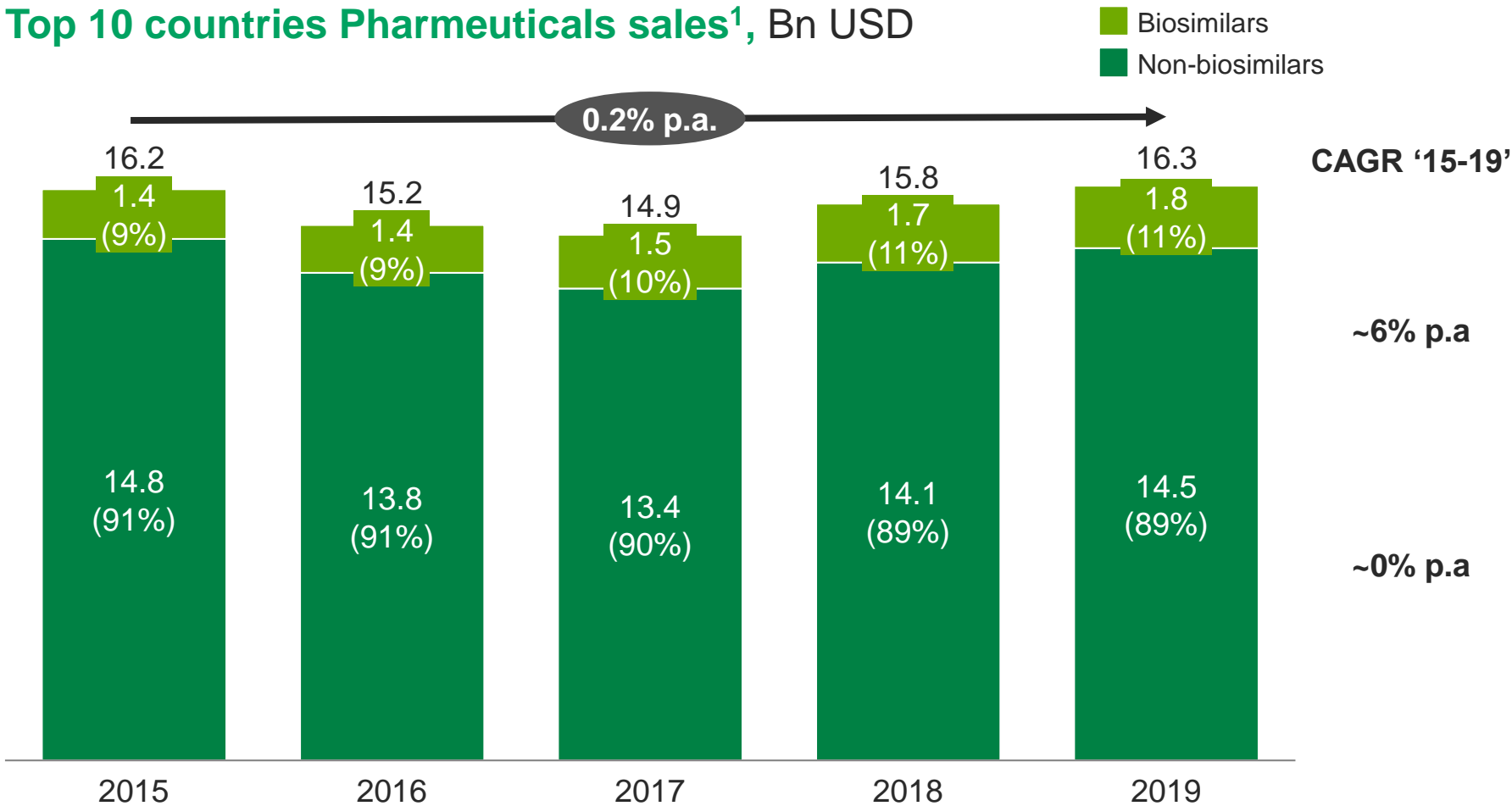
 Partially

 No

| Main production process | Description | Complexity | Trend | Existing technology in Africa? |
|---|--|---|---|---|
| Biosimilars  | Technology for the production of a bio-equivalent to a biologic drug |  High | Need to control biological processes  | Patent expiry of biologic drugs regulatory framework being clarified  |
| Oncology  | Biological drugs treating oncology |  High | Need to control of biological processes  | Strongly growing therapeutic area with high prices  |
| Hormones  | Production of sex hormones or hormones of the adrenal cortex (e.g. cortisol) |  High | Need to control the process that can be harmful to employees  |  |
| Injectables freeze-dried  | Industrial process used to improve the stability of highly labile biopharmaceuticals |  High | Time and energy consuming process, small series  | Market driven by vaccines and insulin  |
| Inhalers of dry powder  | Products mainly used for respiratory conditions such as asthma |  High | -  | Market driven by needs for asthma and certain systemic diseases (diabetes)  |

3 Biosimilars products grew ~6% a year over the past 4 years, though they constituted only 10% of demand in the 10 largest African markets

Top 10 countries Pharmaceuticals sales¹, Bn USD



The market for biological drugs is driven by:

- Growth in R&D spending for **biological drugs worldwide and the arrival of new molecules on the market**
- Increase in **capital invested in biopharmaceuticals** by pharmaceutical players worldwide (imports) and in the Africa region
- Increased **public acceptance of innovative therapies**

5 companies are currently producing biosimilars in Africa - e.g., Médis (Tunisia), Sothema (Morocco), Frater – Razes (Algeria)

1. Including Algeria, South Africa, Morocco, Tunisia, Egypt and French Speaking West Africa

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**

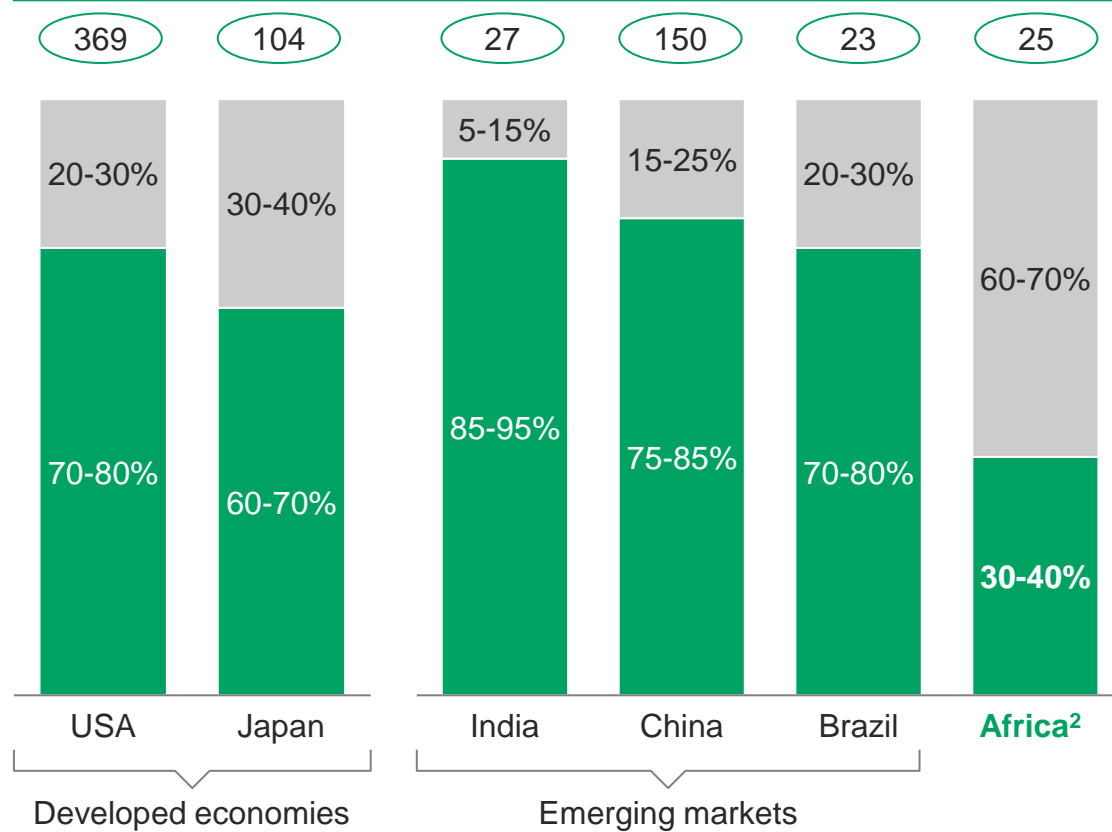
1 African countries lag behind international benchmarks as their overall pharmaceutical production covers 30–40% of demand, with major disparities among countries



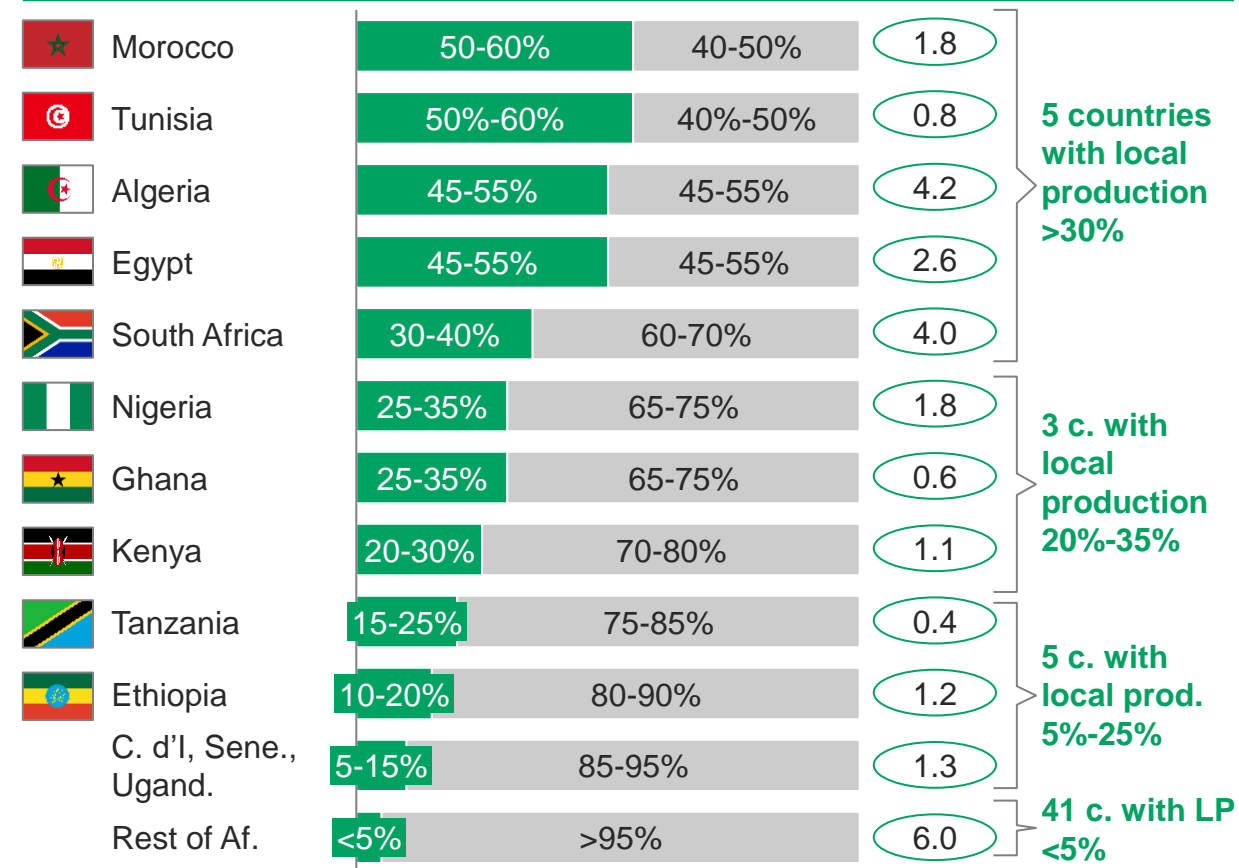
Share of pharmaceutical market value per country between imports and local production 2019¹

X 2019 market size in Bn USD ■ Local production ■ Imported

Africa vs rest of the world



Deep-dive on African countries



1 Or latest available 2 Weighted average computed based on each country's market value 3 Local production

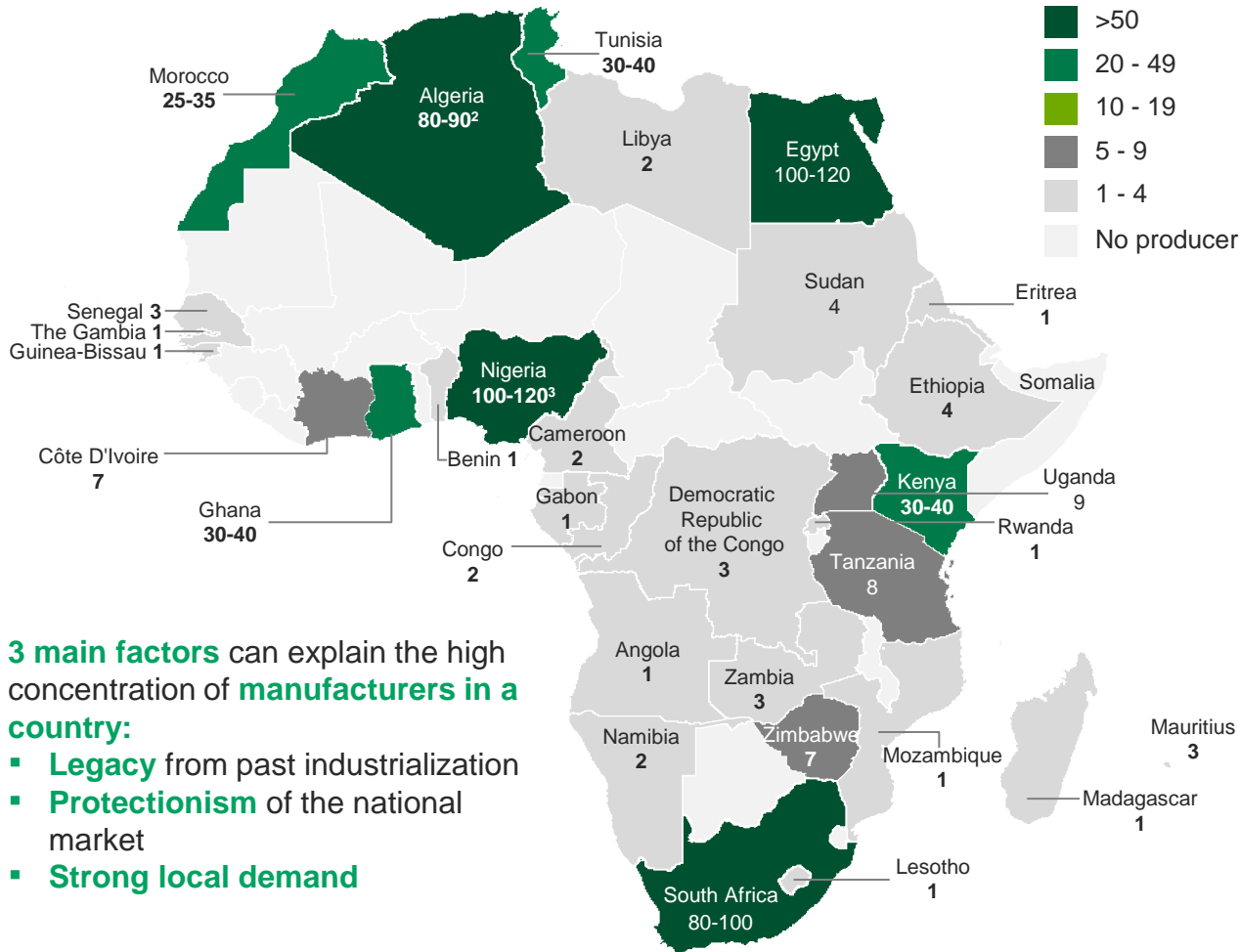
SOURCES: Export Inspection Council of India (2016), INSEE (2018), U.S. Commerce Department (2017), National Strategy and Plan of Action for Pharmaceutical Manufacturing in Ethiopia (2015), FEAPM (2018), UNIDO Kenya report(2011), Flanders Brazil (2018), Japanese Ministry of Health, Labour and Welfare (2019), Oxford Business Group – Egypt regulating pharmaceuticals production (2012) & Tunisian pharmaceutical industry is looking to export more (2016), Fitch African country reports (2019), BMZ report on Tanzania and Kenya (2017), South African government report, OECD report – Competition issues in the distribution of pharmaceuticals in Senegal (2012), Trademap (2019), Eurostat, Expert interviews

1 There are ~600 manufacturers in Africa, mostly concentrated in 8 countries, representing ~80% of the total production



Africa's pharmaceutical manufacturers by country

2020, total = ~600

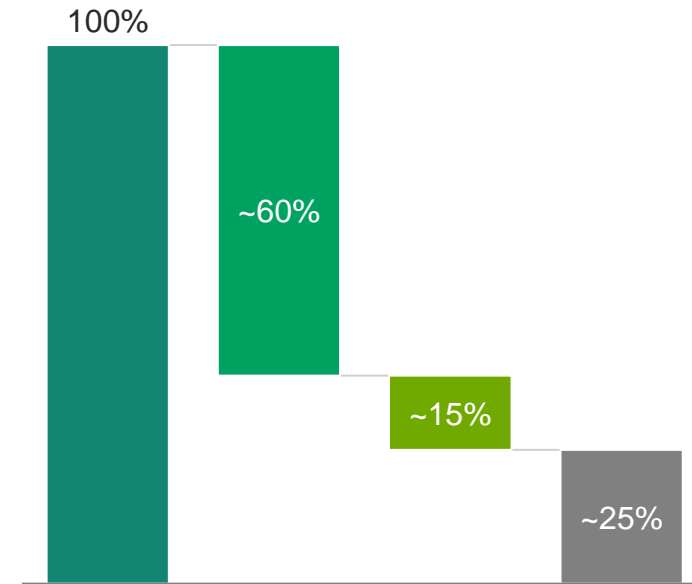


3 main factors can explain the high concentration of **manufacturers in a country**:

- **Legacy** from past industrialization
- **Protectionism** of the national market
- **Strong local demand**

Pharmaceutical manufacturers by ownership, 2020, total sample = ~400

2020, total sample = ~400



BEKER LABORATOIRES

aspEN PHARMACARE

SANOFI

TOBINCO PHARMACEUTICALS LIMITED

adcock ingram adding value to life

Mylan

MINAPHARM PHARMACEUTICALS

gsk GlaxoSmithKline

African manufacturing capacities are concentrated in 8 countries, agglomerating ~80% of the total local production

Only 4 countries have more than 50 manufacturers, while 22 countries have no local production

Local manufacturers tend to be sub-scale, especially in Kenya and Nigeria



¹ Multi-national companies

² In April 2019, the government reported on the existence of 87 active pharmaceutical producers according to Fitch's report for Algeria

³ Over 120 pharmaceutical manufacturers in Nigeria according to UNIDO country report, 2011





Source: Fitch, Capita IQ, UNIDO, Presse search, Companies websites

2 Along the industry value chain from R&D to product packaging, very few of the steps are located in the continent, resulting in a limited production integration level



OUTSIDE-IN VIEW

Very limited (<10 manufacturers)
 Limited (10-49 manufacturers)
 Moderate (50-100 manufacturers)
 High (100+ manufacturers)

| Status (# of manufacturers ¹) | | Value Chain | | | |
|---|------------------|---|---|---|---|
| | | R&D  | API ²  | Manufacturing  | Packaging  |
| Small molecule (e.g., paracetamol) | Local | Very limited (<5) | Very limited (<5) | Moderate (~80) | High (>300) |
| | MNC ³ | Very limited (<5) | Limited (~10) | Moderate (~100) | High (>150) |
| Large molecule (e.g., biosimilars, vaccines) | Local | N/A | N/A | Very limited (<10) | Very limited (<10) |
| | MNC | Very limited (<10) | Very limited (<5) | Very limited (<10) | Moderate (~20) |

- The vast majority of pharmaceutical manufacturing industry is **focused on downstream drug products and packaging**
- Local manufacturers **focus more on small molecules and are less integrated** than MNCs along the value chain:
 - **Less than 20 API manufacturers were identified** with limited product portfolios² – producing for example quinine, that is used to treat malaria
 - **R&D capacities are very limited** on the continent and mostly located in South Africa, especially when it comes to local manufacturers

¹ Possibility to have double-counting as companies can be involved in different part of the value chain

² API manufacturers are located in South Africa (e.g., Pharma Q), Ghana (e.g., Lagray Chemical), and Democratic Republic of the Congo (e.g., Pharmakina)

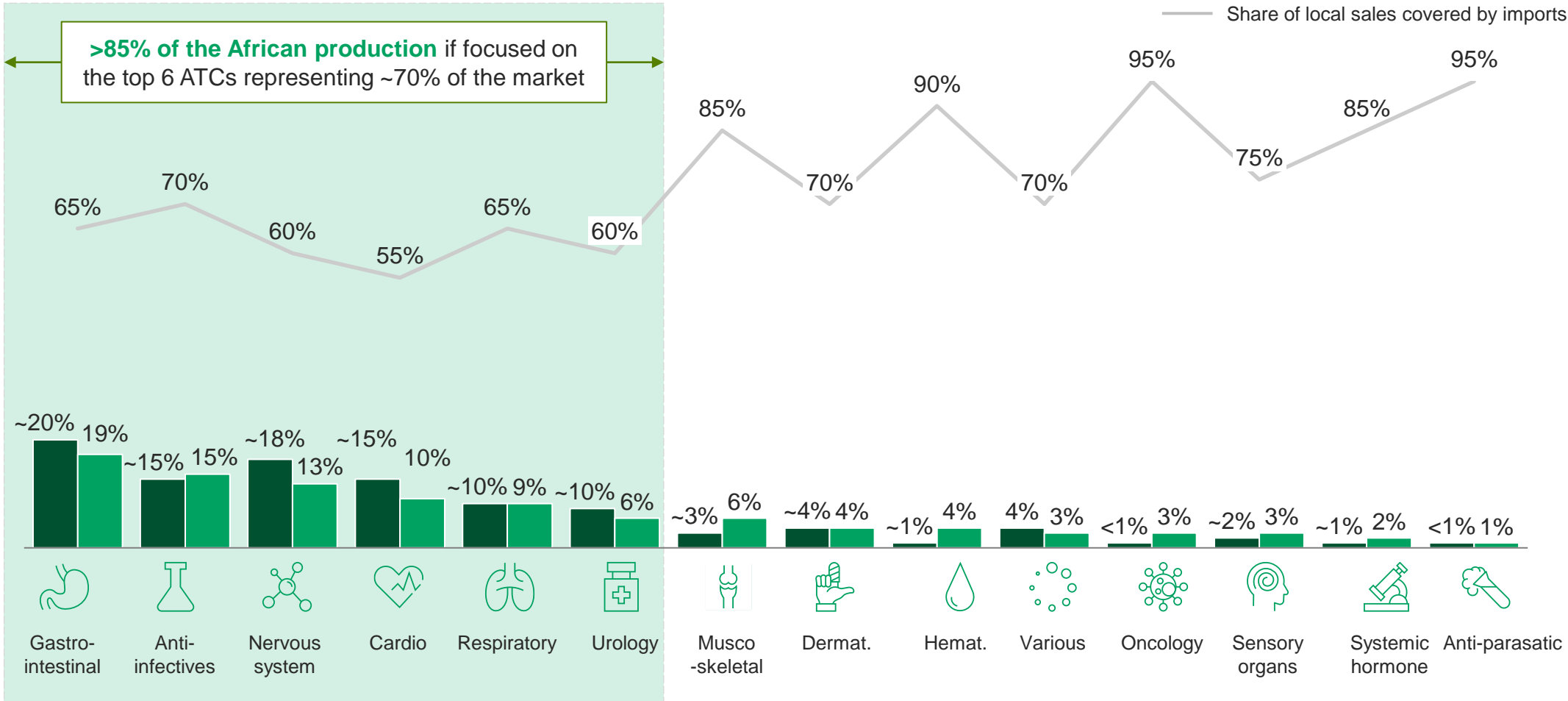
³ Multi-national company

3 The African pharmaceutical production is focused on the top 6 ATCs on the continent, concentrating >85% of production for ~70% of sales



Total African pharmaceutical production in value split by ATC^{1,2} and share of imports in pharmaceutical sales

2019, %



The African production is focused on the top 6 ATCs, representing **85% of local production and ~70% of the market**

On the contrary, there is **limited production capacities for the rest of ATCs (e.g. infectiology), resulting in high level of imports to supply the market**

1 Anatomical Therapeutic Chemical

2 The analysis includes data on the private markets of Egypt, Algeria, Tunisia, Morocco, South Africa, Burkina Faso, Senegal, Benin, Cameroun, Côte d'Ivoire, Congo, Gabon, Guinée, Mali, Niger, Tchad, Togo

4 6 key barriers decrease local pharmaceuticals manufacturers' competitiveness and prevent the development of new actors



NON EXHAUSTIVE

Description

Interview quotes

Difficult access to markets



- Lack of **GMP** (General Manufacturing Practices) and WHO pre-qualifications
- Lack of **harmonization of regulations** with neighboring countries to enable exports
- **Inability to compete on price** due to low plant utilization and small addressable markets

“**African markets are very fragmented**, there is **no harmonization of regulations** across countries that could enable us to export and thereby gain economies of scale”, *Former North Africa VP for a pharma MNC*

Lack of financing



- Lack of access to affordable funding, which **restricts cashflow and limits investments in qualifications and business development** that improve competitiveness

“It is hard for small local manufacturers to access **affordable funding over a long time**”, *McKinsey pharmaceutical sector expert*

Weak logistics and infrastructures



- **Weak infrastructure**, including poor roads and ports, limiting supply and exports
- **Strong domination of foreign actors for pharmaceutical imports/exports**
- **Unreliable and costly power and internet** often resulting in higher costs than international competitors

“A key element in developing a pharmaceutical plant is to **have the infrastructure that enables supply and exports: in Africa it is often difficult**”, *CEO of a North-African pharma company*

Talent shortage



- Shortage of **skilled technicians and scientists** leading to lack of know-how for new drug production, low regulatory capacity, and quality issues
- Quality and quantity issues driven by **lack of schools, focus of curriculum on clinical pharmacy, and limited on-going training for upskilling**

“When you want to launch a new plant on the continent, it is often difficult to **find the right skilled technicians and scientists**”, *PE investor*

Inadequate regulatory environment



- Lack of **supportive policy or preferential treatment** around market access, regulatory approval, and pricing results in inability of local producers to catch up to international firms

“Countries that have managed to develop an industry on the continent are those which have **set in place supportive policies** for local actors”, *Former North Africa VP for a pharma MNC*

Lack of national governance



- Inadequate governance by regulatory bodies, e.g., PPB¹, resulting in a **flood of substandard and counterfeit drugs**
- Political instability in some countries **making long-term investments risky**

“**The governance and regulation is often insufficient**, resulting in a **flood of counterfeit drugs**”, *Former country manager of Nigeria and East Africa for a pharma MNC*

¹ Pharmacy and Poisons Board in Kenya
SOURCE: Fitch solutions, WHO, World Bank, expert interviews

7 strategic orientations arose from the diagnostic and informed the thinking around the development of a 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 and economically competitive 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 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 vision and 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 4 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

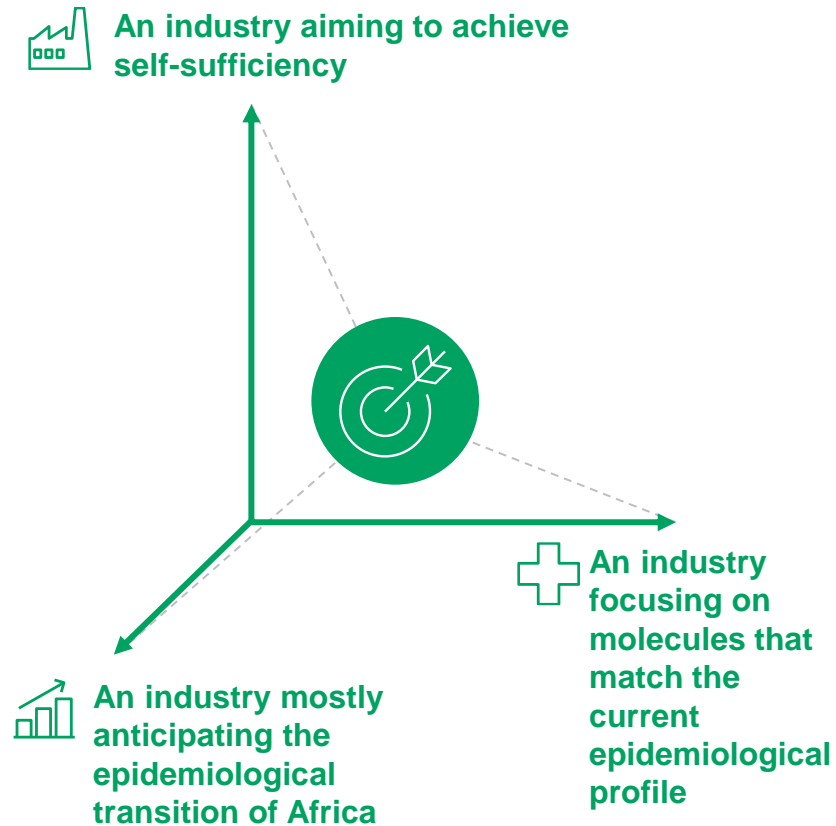


Prioritization of the investment opportunities identified based on the African Development Bank's comparative advantages



A sustainable path to the pharmaceutical industry would necessarily be a combination of these 3 stylized 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 (through Enabler III)

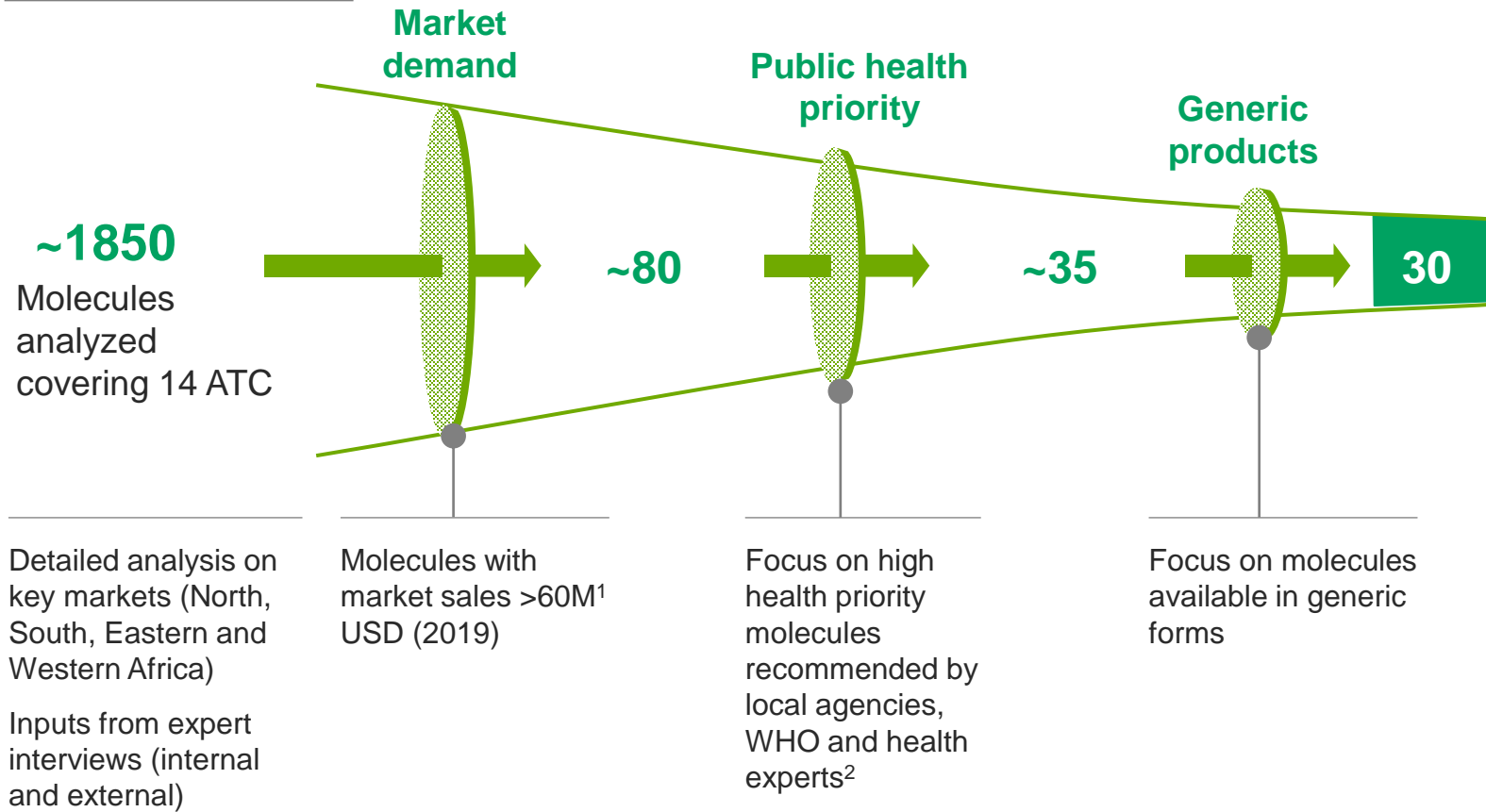
Developing a sustainable industry could be possible by **combining the economic impact of security of supply with the public health advantages of addressing the new disease burden (NCD), while increasing R&D capacities**

1. Non-Communicable Diseases

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



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

Inputs from expert interviews (internal and external)

| 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

A target of 45-55% of local production would be highly ambitious yet achievable by gathering a diversity of partners around AfDB

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

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

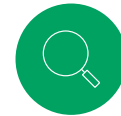
Help the implementation of quality industry standards for the African continent

~20%



50%

Of all pharma manufacturers adhering to GMP¹ standards



ENABLER III

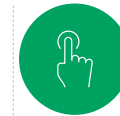
Seed the creation of R&D capacities focusing on Africa specific diseases and needs

~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

| | 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 |

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

With fragmented trade and inconsistent logistics/freight capacities in Africa, defining 4 pharmaceutical hubs could be enabled 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 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

| | 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 |

There are 10 vaccines manufacturing projects in Africa, with different potentials to engage partners based on market potential, country costs, track record and project completion

Preliminary | Non exhaustive | Projects identified as potential targets for the AfDB based on availability of information and respect of geographical balance

| Country | Manufacturer | Market potential | Track record | Project (incl. type of technology) | Level of completion | Attractiveness level |
|--------------|-----------------------------------|---|--|--|--|----------------------|
| South Africa | Biovac | Small local market (~60Mn inhabitants) but high GDP per capita | Existing local industry and plant since 2003 | Project to manufacture vaccines in South Africa for a budget of \$300Mn | Project almost driven to its end, and more than 2/3rd are already financed | |
| | Aspen Pharmacare | Small local market (~60Mn inhabitants) but high GDP per capita | First African country to manufacture COVID-19 vaccines | Preliminary agreement with Janssen Pharmaceuticals, Inc. to manufacture COVID-19 vaccine, Ad26.CO2-S | N/A ² | |
| Egypt | Egy Vac (Vacsera) | Size of the domestic market guaranteeing absorption of the supply | Production of different drug substances already | \$1.5Mn invested by WHO to produce 500K doses of influenza Vx Cooperation with China for COVID-19 Vx | N/A ² | |
| Senegal | Institut Pasteur Dakar | Very small local market (~20Mn inhabitants) but high regional potential | Existing local industry and plant since 1913 | Agreement with biotech group Univercells to package COVID-19 vx (viral-vector) Budget is of \$200Mn, for 300Mn doses | Full production is only planned for the second half of 2022 | |
| Algeria | Institut Pasteur Algeria | Small local market (~45Mn inhabitants) | No data available on vaccines in Algeria since 2017 | No project announced since agreement signed in 2017 with Sanofi Pasteur to produce 10Mn to 20Mn of Hexavalent and Tetravalent vaccines | No project announced yet | |
| Morocco | Institut Pasteur Morocco | Small local market (~40Mn inhabitants) | Existing local industry and plant since 1967 | Produce drug substance infectious diseases and intoxications Vx and agreement with Sinopharm to produce COVID-19 vaccines | Plan developed but low completion level | |
| Ethiopia | EPHI: Eth Public Health Institute | Important size of the population, but low GDP per capita | Existing local industry and plant since 1995 | Production (DS, F&F and packaging) vaccines for rabies, meningitis, yellow fever, cholera and typhoid fever with FINLAY Institute | Low completion level and no investment yet | |
| Nigeria | Biovaccines Nigeria Limited | Size of the domestic market guaranteeing absorption of the supply | No existing proof of the quality of work of the lab | Plan to produce most demanded vaccines Plan to acquire modular fill and finish lines for emerging diseases vaccines | N/A ¹ | |
| | Innovative Biotech | Size of the domestic market guaranteeing absorption of the supply | Existing local R&D plant since 2005 | Project to establish vaccine manufacturing plant for production of Vaccines in Nigeria | No precise plan for manufacture announced | |
| Tunisia | Institut Pasteur Tunis | Very small local market (~12Mn inhabitants) and strategic positioning for exports | One of leading world BCG labs, founded in 1893 | <i>No project announced</i> | No project announced yet | |

Note: President Kagame announced in April: “Rwanda is working with partners to bring the first mRNA manufacturing facility to Africa”

1. Information not publicly available

Source: fDi Intelligence based on Willis Towers Watson Global Remuneration Planning Report 2018/19, iMercer and national statistics, World Tariff Profiles, Global Tax Rates KPMG, Enerdata 2019, Economics Plant Worldbank, World Freight Rates 2020, Capital IQ, Press search, Companies websites, VMPA study

Enabler IV will pave the way for increased vaccines manufacturing in Africa¹

Context

Africa heavily relying on imports for **vaccines** with local production capacities addressing less than **1% of the local demand in value**

Rationale

Over-reliance of African countries on imported vaccines, which can lead to tensions during crisis (e.g. Covid-19)
 Potential to sustainably manufacture vaccines in Africa still to be confirmed
 African Union and Africa CDC launched **Partnerships for African Vaccine Manufacturing (PAVM)**

Ambition

850Mn of local routine vaccines to reach the goal of 60% of African demand produced locally in 2040

Strategic axis

a Support the development of manufacturing plants

b Shape a vehicle to pool the demand for African countries

c Support hub anchors development

Description

Financing the development of vaccine manufacturers

- Long-term financing of investment projects through direct lending and/or equity
- Technical assistance to local manufacturers and co-investors (e.g. IP technical know-how transfer, sourcing)

Support the set-up of a take or pay type of provision with 3 mechanisms to secure offtakes for the industry:

- Securing offtakes from key markets (incl. the ones expected to transition from Gavi), leveraging the public and the private sector
- Secure more vaccines sourced from Africa by advocating and ensuring percentage of African procurement

Support selected countries as vaccines hubs:

- Public sector financing of public contribution to infrastructure
- Policy, institutional and regulatory advice

Strategic axis KPIs

Baseline 2020

Aspiration² 2030

Share of local production of vaccines

<1%

60%

Production units

10 small production units of less than 2 Mn each

5 additional manufacturing plants of 30 – 300Mn units each

Doses production capacity

10-12 millions

150Mn - 1.5Bn

Investment in vaccines manufacturing

\$500Mn – \$1Bn³ (estimated on the basis of \$50-100 million investment for each unit based on press research and expert input).

~\$600Mn – \$1,2Bn³

1. See full section on Vaccine manufacturing slides 46 – 54.
 2. Calculations based on an 2040 ambition, but all budgets need to be provisioned by 2030 to meet ambition
 3. Ranges depending on different technologies and parts of the value chain considered

The production of 850 Mn vaccines would involve a CAPEX of \$600Mn-\$1.2Bn depending on the scenario that is likely to happen



Different scenarios can be used to estimate the overall CAPEX need







| | | | |
|---|--|---|---|
| Scenario 1: mRNA takeoff | <ul style="list-style-type: none"> ▪ 4 mRNA ▪ 1 Egg based | \$125Mn per mRNA plant \$113Mn per Egg based plant ~\$600 Mn | \$209Mn per mRNA plant \$171Mn per Egg based plant ~\$1 Bn |
| | | Import API: fill & finish only | |
| Scenario 2: Bio-reactor based takeoff | <ul style="list-style-type: none"> ▪ 4 Bio-reactor based ▪ 1 Egg based | \$120Mn per Bioreactor-based plant \$113Mn per Egg based plant ~\$600 Mn | \$265Mn per Bioreactor-based plant \$171Mn per Egg based plant ~\$1.2 Bn |
| | | Full domestic: drug substance manufacturing and fill & finish | |

The production of 850Mn vaccines in Africa in 2040 would involve a CAPEX of \$600Mn - \$1.2Bn depending on the technology

A trade-off between promoting self-sufficiency with full-domestic production and feasibility by importing API will be required

These overall CAPEX can be used to estimate CAPEX in 2030, as they need to be provisioned to meet Africa CDC ambitions in 2040

Out the 6 critical enablers* for the development of vaccines manufacturing on the continent, the AfDB can play a key role on 3 of them

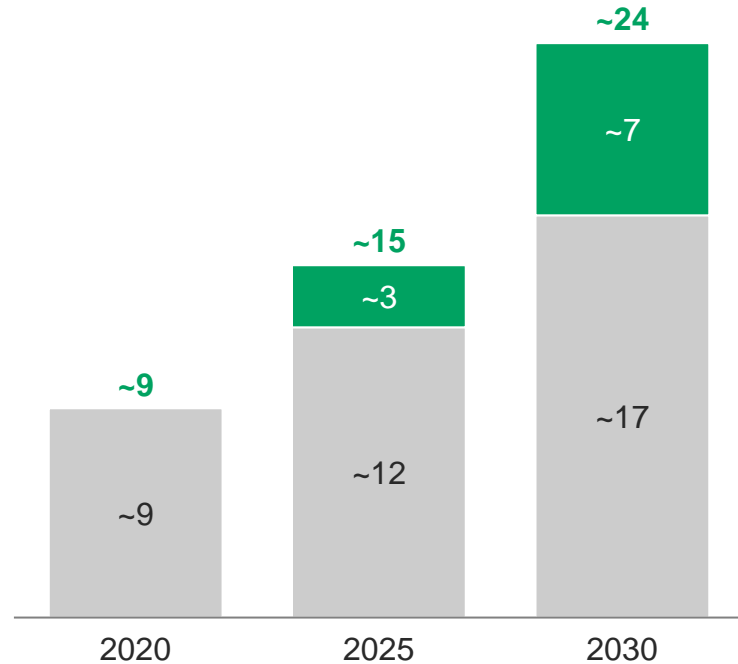
| Enablers | Key Summit insights | Unique role of the AfDB on vaccines |
|---|---|---|
| A Agenda-setting and coordination  | <ul style="list-style-type: none"> Act now to take advantage of momentum, while establishing long-term political commitment Make thoughtful choices for the broader continent Break down barriers to flow of vaccines between countries Establish vaccine raw materials industries across the continent | <ul style="list-style-type: none"> <i>None addressable by AfDB</i> |
| B Regulatory strengthening  | <ul style="list-style-type: none"> 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 | <ul style="list-style-type: none"> <i>None addressable by AfDB**</i> |
| C Demand certainty Procurement pooling mechanism  | <ul style="list-style-type: none"> Create long term supply contracts Concerted effort required to achieve pooled demand | <ul style="list-style-type: none"> Potential to establish a pooled procurement mechanism for and secure offtake agreements for locally produced vaccines |
| D Access to finance  | <ul style="list-style-type: none"> 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 | <ul style="list-style-type: none"> Establish dedicated African vaccines manufacturing fund |
| E Technology Transfer & IPs. Talent & know-how  | <ul style="list-style-type: none"> 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 | <ul style="list-style-type: none"> <i>Enabler addressed within the pharmaceutical manufacturing strategy</i> |
| F Infrastructure development  | <ul style="list-style-type: none"> 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 | <ul style="list-style-type: none"> Invest in vaccine manufacturing facilities Support the expansion of the transportation networks |

*Two additional enablers have been included in the planning; namely, Convening & Coordination and Vaccine R&D centres

** Already being addressed by AfDB

The implementation of the plan is estimated to have a GDP impact of ~USD5 Bn and enable the creation of ~500k jobs by 2030, mostly high-skilled

African pharmaceutical industry revenue, locally generated, USD Bn



- Based on targets of **~43% and ~50% local production** by 2025 and 2030 respectively
- Excluding infrastructure investments** as they are not impacting pharma only

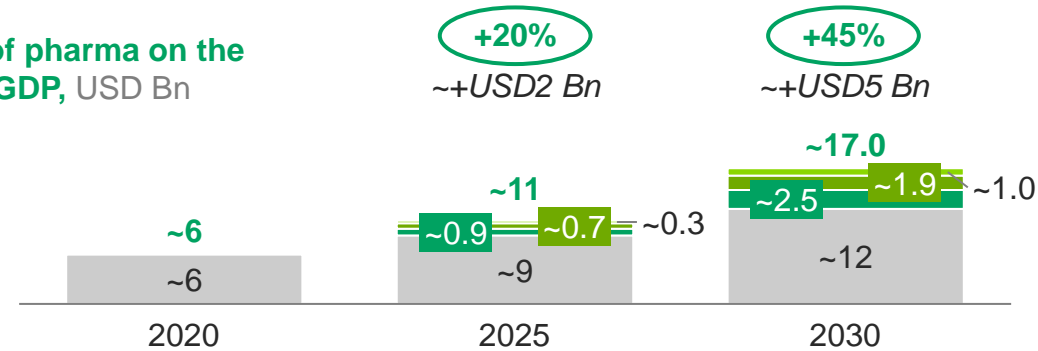
1. Value Added

+X Bn Additional impact **+X%** Additional impact in % of the baseline scenario

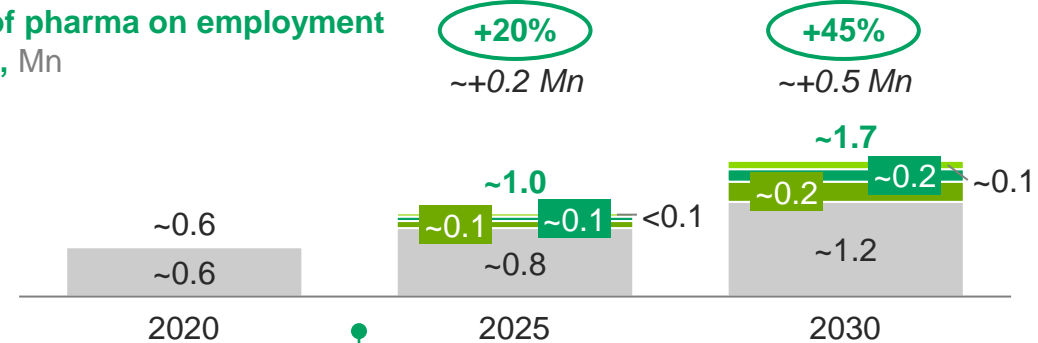
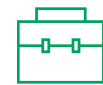
■ Initial impact ■ Direct impact ■ Indirect impact ■ Baseline scenario

Impact of the plan on the African economy

Impact of pharma on the African GDP, USD Bn



Impact of pharma on employment in Africa, Mn



- Computed **based on Input/Output economic analysis** using a multiplier approach (*detailed in appendix*)
- Includes:
 - Initial impact**, e.g. increased VA¹ from pharma manufacturers
 - Direct impact**, e.g. increased VA by excipient producers or distributors
 - Indirect impacts**, e.g. effects of increased spending of manufacturer's employees

On top of the ~USD12 Bn estimated pharma contribution to GDP by 2030, **implementing the strategy could add ~USD 5Bn more**, i.e. 45%

In terms of jobs, the strategy could enable **500k additional job creations by 2030**, enabling the pharma sector to reach ~1.7 Mn jobs

Most jobs would also be **high-skilled jobs** (e.g. pharmacists) that would benefit the African development

~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



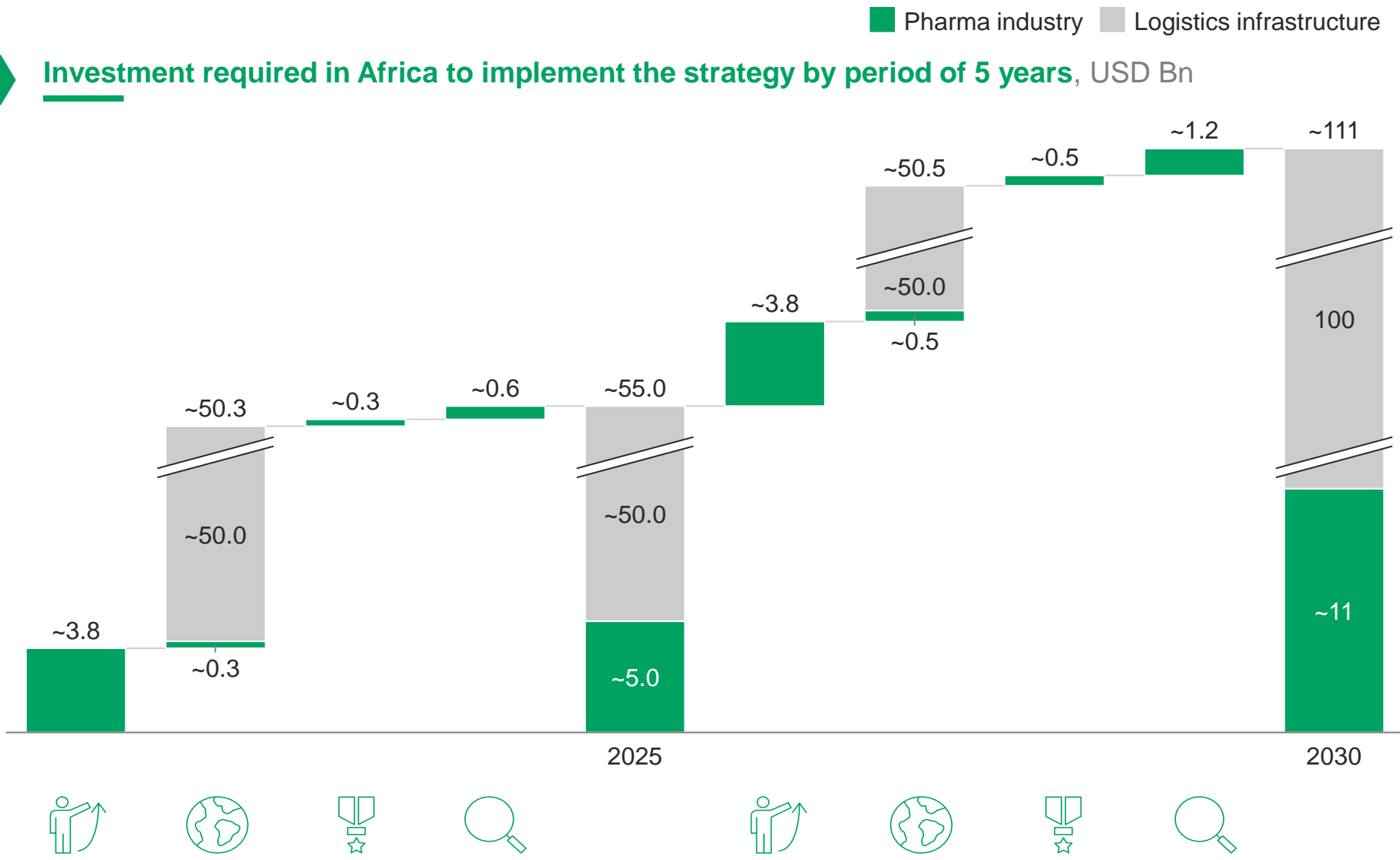
Help the implementation of quality industry standards in line with international benchmarks



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

Pillar and enablers

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

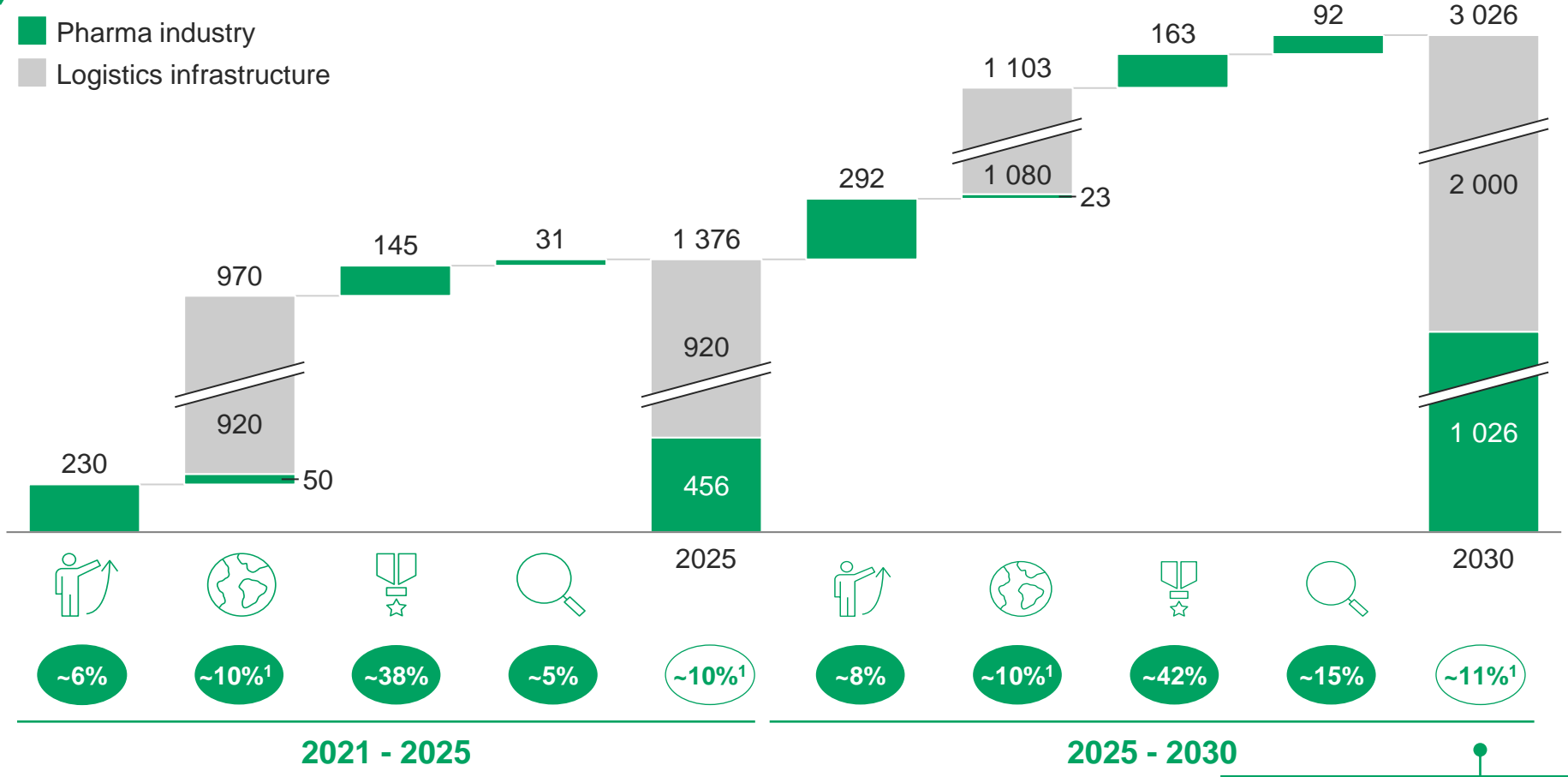
Enable regional logistic integration to foster intra-African trade and the creation of trade hubs

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

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

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



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

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

10 Flagship Programs have been identified to comprehensively cover the pharmaceutical strategy

1. Program to **upscale and transform mid-size African pharmaceutical manufacturers** (esp. gx oral solid forms)



2. **Deal making and attraction program** for pharma-related FDIs on the continent



3. Support program for current African champions to invest in **bioproducts** (incl. vaccines and biosimilars)



4. **Facilitation program to enable efficient pharmaceutical distribution** and create regional hubs



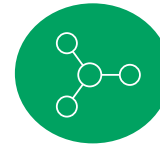
5. Program of **quality improvement and regulation harmonization** to foster intra-continental drug trade



6. **Skills development** program in the pharmaceutical industry



7. Seed support program to **unlock the development of a biotechnology ecosystem in Africa**



8. Integrated program to **support health infrastructure for R&D development**



9. Program to **upscale and transform African vaccines manufacturers**



10. Program to support the development of a vehicle to **pool the demand** for African countries and ensure long-term vaccine **offtake agreements**



What are the AfDB Transformative Flagship Programs ?

- **Flagship programs are bundles of initiatives** combining financial support (both direct and indirect), technical assistance and/or advocacy and which can either be purely SO, NSO or mixed¹
- A single flagship program does not need to combine all of these tools abovementioned
- **The flagship programs can either be fully led and implemented by AfDB or can involve multiple stakeholders** (e.g. DFIs, governments, private sector), with AfDB either leader or active contributor
- This set of flagship programs ensure a **comprehensive coverage** of AfDB strategic dimensions (e.g. strategic pillar and 3 enablers) - *some programs may cover several dimensions*

¹ Programs can be mixed but projects are purely SO or NSO

10 flagship programs have been identified and 23 projects to comprehensively cover the pharmaceutical strategy



PROJECTS DETAILED IN THE NEXT PAGES

| Flagship program | Projects | NSO | SO | Strategic dimensions addressed |
|--|--|-----|----|--------------------------------|
| 1 Program to upscale and transform of mid-size African pharmaceutical manufacturers (esp. oral solid form and generics) | <ul style="list-style-type: none"> 1.A. Long-Term lending to African-based manufacturers through various type of loans to mid-size local manufacturers (~\$10 to 30Mn per player) to support them in upscaling existing capacities or creating new lines/production sites 1.B. Indirect equity to local pharma manufacturers leveraging PE funds (both generalist and pharma-specialized funds) and investment platforms expertise 1.C. Technical Assistance to small to mid-size local manufacturers through grants or trust funds | ✓ | | |
| 2 Deal making and attraction program to attract pharma-related FDIs on the continent | <ul style="list-style-type: none"> 2.A. Grants or Trust Funds to local governments or regional/continental organizations to sponsor regional or national roadshows to attract Tiers-2 and Tiers-3 international players investments in Africa 2.B. Direct lending to international pharma manufacturers to develop manufacturing capacities in Africa or invest in African-based sites 2.C. Technical Assistance to global manufacturers at different stages of project development through grants | ✓ | ⚠ | |
| 3 Upscaling program for mature African-based manufacturers dedicated to bioproducts (incl. vaccines and high-tech biosimilars) | <ul style="list-style-type: none"> 3.A. Direct lending to international pharma manufacturers to develop biosimilar manufacturing capacities in Africa or African Champions to upscale manufacturing capacities on biosimilar products 3.B. Technical Assistance to mature local manufacturers willing to expand their product portfolio with biosimilars, support focusing on industrial processes | ✓ | | |
| 4 Facilitation program to enable efficient pharmaceutical distribution and create regional hubs | <ul style="list-style-type: none"> 4.A. Loans to mid-size distributors to support target players in upscaling existing capacities and network extension 4.B. Indirect equity to local pharma distributors leveraging PE funds (both generalist and pharma-specialized funds) and investment platforms expertise 4.C. Technical Assistance to small to mid-size local distributors through grants | ✓ | | |
| 5 Program of quality improvement and regulation harmonization to foster intra-continental drug trade | <ul style="list-style-type: none"> 5.A. Capability building to upgrade African NMRAs¹ 5.B. Support to the African Medicines Agency (AMA) and African Medicines Regulatory Harmonization (AMRH) Initiatives | | ✓ | |
| 6 Skills development program in the pharmaceutical industry | <ul style="list-style-type: none"> 6.A. Launch of a University Chair dedicated to pharmaceutical research 6.B. Creation of life-long learning curriculums dedicated to pharma skills 6.C. Technical assistance to governments to promote pharma-related training programs (e.g., graduate) | ⚠ | ✓ | |
| 7 Seed support program to unlock the development of biotechnologies in Africa | <ul style="list-style-type: none"> 7.A. Launch of a regional incubator platform dedicated to medical biotechnologies start-ups 7.B. Creation of a Venture Capital fund within the ADB dedicated to seed investments (e.g. Serie A or B) in medical biotechnologies in Africa | ✓ | | |
| 8 Integrated program to support health infrastructure for R&D development | <ul style="list-style-type: none"> 8.A. Grants to university hospitals for the required clinical trials infrastructures 8.B. Incentive system to foster activity of Contract research organizations (CRO) in Africa | | ✓ | |
| 9 Program to upscale and transform African vaccines manufacturers | <ul style="list-style-type: none"> 9.A. Direct lending or indirect equity investment to African-based manufacturers 9.B. Technical assistance to local manufacturers (standalone action or condition for funding) and co-investors and financing of specialized consultancy | ✓ | ⚠ | |
| 10 Program to support the development of a vehicle to pool the demand for African countries and ensure long-term vaccine offtake agreements | <ul style="list-style-type: none"> 10.A. Support to the development of a pooling and wheeling platform to aggregate demand and benefit from economies of scale by advocating and managing cooperation between partners, by financing the pooling platform through grants, and by creating a guarantee fund dedicated to compensate unsold stock and secure offtake | ✓ | ⚠ | |

¹ National Medicines Regulatory Authority

AfDB would lead 5 flagship programs and would actively contribute to the 4 other ones in close cooperation with a variety of stakeholders



xxx Potential leads

Flagship program

★ Led by AfDB

AfDB Role

Other players involved

| | | | |
|--|---|---|--|
| <p>1 Program to upscale and transform of mid-size African pharmaceutical manufacturers (esp. oral solid form and generics) ★</p> | <ul style="list-style-type: none"> Program Leader | <ul style="list-style-type: none"> DFIs (e.g. Proparco, IFC, Asian Development Bank, Islamic Development Bank, EBRD) Local governments Industrial organizations (e.g. UNIDO) | <ul style="list-style-type: none"> Private sector (e.g. PE funds : Afric Invest, CDC Investment Works) Specialized consultancies Continental Organization (e.g. AU) |
| <p>2 Deal making and attraction program to attract pharma-related FDIs on the continent</p> | <ul style="list-style-type: none"> Advocacy and funding role | <ul style="list-style-type: none"> DFIs (e.g. FCDO) Local governments (e.g. Investment promotion agencies) Regional Organizations (e.g. EAC, ECOWAS, COMESA, SADEC) | <ul style="list-style-type: none"> Continental Organization (e.g. AU) Industrial organizations (e.g. UNIDO, AU/Nepad) Specialized consultancies |
| <p>3 Upscaling program for mature African-based manufacturers dedicated to bioproducts (incl. vaccines and high-tech biosimilars) ★</p> | <ul style="list-style-type: none"> Program Leader | <ul style="list-style-type: none"> DFIs (e.g. Proparco, IFC, EBRD) Local governments Continental Organization (e.g. AU) | <ul style="list-style-type: none"> Industrial organizations (e.g. UNIDO) Private sector (e.g. PE funds : Afric Invest, CDC Investment Works) |
| <p>4 Facilitation program to enable efficient pharmaceutical distribution and create regional hubs ★</p> | <ul style="list-style-type: none"> Program Leader | <ul style="list-style-type: none"> DFIs (e.g. IFC, FCDO) Private sector (e.g. PE funds) Specialized consultancies International donors (e.g. Mastercard Foundation) | <ul style="list-style-type: none"> Industrial organizations (e.g. UNIDO) Continental organizations (e.g. CFTA, AU) |
| <p>5 Program of quality improvement and regulation harmonization to foster intra-continental drug trade</p> | <ul style="list-style-type: none"> Advocacy, coordination and funding role | <ul style="list-style-type: none"> DFIs (e.g. World Bank, AFD) Regional Organizations (e.g. African Union, EAC, ECOWAS, Africa CDC) Continental Organization (e.g. AU, AMA, CFTA) | <ul style="list-style-type: none"> Local Governments (e.g. NMRAs) Industrial organizations (e.g. AUDA-NEPAD) International organizations (e.g. WHO) |
| <p>6 Skills development program in the pharmaceutical industry</p> | <ul style="list-style-type: none"> Funding role | <ul style="list-style-type: none"> DFIs (e.g. World Bank) Local governments (e.g. Ministry of Education) Private sector (e.g. manufacturers) | <ul style="list-style-type: none"> Industrial organizations (e.g. UNIDO, AUDA-NEPAD) Public and private universities and training institutes Continental Organization (e.g. AU) |
| <p>7 Seed support program to unlock the development of biotechnologies in Africa ★</p> | <ul style="list-style-type: none"> Program Leader | <ul style="list-style-type: none"> DFIs (e.g. Proparco, IFC) Continental Organization (e.g. AU) International Donors (e.g. BMGF, Mastercard Foundation) | <ul style="list-style-type: none"> Private sector (e.g. PE funds -Afric Invest, CDC Investment Works- Venture Capital and Industrial players) Specialized consultancies |
| <p>8 Integrated program to support health infrastructure for R&D development</p> | <ul style="list-style-type: none"> Advocacy and funding role | <ul style="list-style-type: none"> DFIs (e.g. Proparco, IFC, European Investment Bank) Local governments and Regional Organizations Continental Organization (e.g. AU) | <ul style="list-style-type: none"> Private sector (e.g. PE funds: IFHA) Specialized consultancies International organizations (e.g. WHO) International Donors (e.g. BMGF, Mastercard Foundation) |
| <p>9 Program to upscale and transform African vaccines manufacturers ★</p> | <ul style="list-style-type: none"> Program Leader | <ul style="list-style-type: none"> Members of the Partnerships for African Vaccine Manufacturing (PAVM) Industrial organizations (e.g. UNIDO) | <ul style="list-style-type: none"> Local governments (e.g. Ministries of Health) DFIs (e.g. Proparco, IFC, Asian Development Bank) Private sector (e.g. PE funds: Africa Invest, CDC Investment) |
| <p>10 Program to support the development of a vehicle to pool the demand for African countries and ensure long-term vaccine offtake agreements</p> | <ul style="list-style-type: none"> Advocacy, coordination and funding role | <ul style="list-style-type: none"> Partnerships for African Vaccine Manufacturing (PAVM) (Africa Union, Africa CDC & Mastercard Foundation) (potential program leaders) | <ul style="list-style-type: none"> DFIs (e.g. World Bank, AFD) Guarantee funds (e.g. the Development Guarantee Group) Regional Organizations (e.g. EAC, CEDEAO) |

The 10 Transformative Flagship Programs will enable AfDB to achieve 2030 goals defined in the strategy



Immediate impact
 Secondary impact

| KPI | Strategic Pillar | | | Enabler I | Enabler II | Enabler III | Enabler IV | |
|---|--|---|---|---|--|--|--|--------------|
| | Targeted production of local manufacturers | Targeted production of mid-sized global and Af. champions | Number of African companies producing biosimilars | Intra-African pharma exports to USD1 Bn by 2030 | Of all pharma manufacturers adhering to GMP ¹ standards | Pharmaceutical R&D investment in the continent by 2030 | Targeted production of local manufacturers | |
| | 2030 Target | 35 Bn units | 55 Bn units | 15 | USD 1 Bn | 50% | USD 2.4 Bn | 850 Mn doses |
| 1. Program to upscale and transform of mid-size African pharmaceutical manufacturers (esp. oral solid form and generics) | | | | | | | | |
| 2. Deal making and attraction program to attract pharma-related FDIs on the continent | | | | | | | | |
| 3. Upscaling program for mature African-based manufacturers dedicated to bioproducts (incl. vaccines and high-tech biosimilars) | | | | | | | | |
| 4. Facilitation program to enable efficient pharma distribution and create regional hubs | | | | | | | | |
| 5. Program of quality improvement and regulation harmonization to foster intra-continental drug trade | | | | | | | | |
| 6. Skills development program in the pharmaceutical industry | | | | | | | | |
| 7. Seed support program to unlock the development of biotechnologies in Africa | | | | | | | | |
| 8. Integrated program to support health infrastructure for R&D development | | | | | | | | |
| 9. Program to upscale and transform African vaccines manufacturers | | | | | | | | |
| 10. Program to support the development of a vehicle to pool the demand | | | | | | | | |

1 GMP: Good Manufacturing Practices

AfDB would leverage its financial instruments in a customized manner for each of the flagship programs



| Flagship program | Line of credit | Loans | Equity | Trade finance | Grant | Guarantee | Trust Funds | Risk Management |
|---|----------------|-----------------------------------|--|---|--|--|--------------|----------------------|
| 1 Program to upscale and transform mid-size African pharmaceutical manufacturers | ✓ | ✓ Fixed Spread Loan | ✓ Direct Equity, indirect equity and subordinated debt | | ✓ Technical assistance, Grants and Reimbursable grants | ✓ Partial Credit Guarantee | ✓ Trust Fund | |
| 2 Deal making and attraction program to attract pharma-related FDIs on the continent | ✓ | ✓ Fixed Spread Loan | | ✓ Risk Participation Agreements Trade Finance Lines Of Credit | ✓ Technical assistance | ✓ Partial Risk Guarantee, Partial Credit Guarantee | | ✓ Risk Mgt. Products |
| 3 Upscaling program for mature African-based manufacturers dedicated to bioproducts | ✓ | ✓ Fixed Spread Loan | ✓ Direct Equity, indirect equity and subordinated debt | ✓ Risk Participation Agreements Trade Finance Lines Of Credit | ✓ Technical assistance | ✓ Partial Risk Guarantee, Partial Credit Guarantee | | ✓ Risk Mgt. Products |
| 4 Facilitation program to enable efficient pharma distribution and create regional hubs | ✓ | ✓ Fixed Spread Loan | ✓ Direct or indirect equity and subordinated debt | | ✓ Technical assistance | ✓ Partial Credit Guarantee | ✓ Trust Fund | |
| 5 Program in favor of quality improvement and regulation harmonization to foster intra-continental drug trade | | ✓ ADF loan | | | ✓ Technical assistance | | ✓ Trust Fund | |
| 6 Skills development program in the pharmaceutical industry | | ✓ Fully flexible loan | | | ✓ Technical assistance, Grants and Reimbursable grants | | ✓ Trust Fund | |
| 7 Seed support program to unlock the development of biotechnologies in Africa | | | ✓ Direct or indirect equity | | ✓ Technical assistance | ✓ Partial Risk Guarantee, Partial Credit Guarantee | | |
| 8 Integrated program to support health infrastructure for R&D development | | ✓ ADF Loan or fully flexible loan | | | ✓ Technical assistance | | | |
| 9 Program to upscale and transform African vaccines manufacturers | | ✓ Fixed Spread Loan | ✓ Direct Equity, indirect equity and subordinated debt | | ✓ Technical assistance | | ✓ Trust Fund | |
| 10 Program to support the development of a vehicle to pool the demand for African countries and ensure long-term vaccine offtake agreements | ✓ | ✓ ADF loan | | ✓ Risk Participation Agreements Trade Finance Lines Of Credit | ✓ Grants and Reimbursable grants | ✓ Partial Risk Guarantee, Partial Credit Guarantee | ✓ Trust Fund | ✓ Risk Mgt. Products |



Thank You for your interest.
We welcome your support in implementing the AP.