Scaling pharmaceuticals manufacturing in Kenya

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GREAT for GROWTH
BRITAIN & NORTHERN IRELAND

UKaid
from the British people

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We have leveraged multiple stakeholders and industry players in developing a comprehensive view of the industry landscape

Multiple industry players have been engaged and market data leveraged…

+10

Local manufacturers, associations, industry players and experts

5

Government and other development agencies[1]

+10

Publicly available databases and internal proprietary databases leveraged[2]

…in developing a detailed view on the opportunities to scale pharmaceuticals manufacturing in Kenya

1. KEMSA, Pharmacy and Poisons Board, Kenya Healthcare Federation, IFC, et. al
2. African Pharmaceuticals report, Product Master Rolls, Pharmaceutical manufacturing plan for Africa, et. al

Executive Summary (1/2)

Market overview

The **EA pharmaceutical market is ~$3.4bn** expected to grow at 4-6% driven by improving population dynamics, government support, and addressing the growing disease burden - **Kenya is the largest market at $1.2bn** and expected to **grow at 7%**

Kenya is the most advanced manufacturer of pharma in the region and is also an exporter to the broader EAC

In Kenya, government and donors are responsible for ~2/3 of the procurement with KEMSA (government buyer) as the largest buyer:

- Public sector imports oncology, insulin, and cardiovascular medicines
- Social sector[1] imports ARVs, Vaccines, Antimalarials and TB medicines

>70% of the market value is in solids and liquids, with leading product categories in anti-virals, anti-bacterials, and immunological agents

Majority of the market's value (~70%) is served through imports of which **India is significantly the largest (45%)** importing anti-virals, vaccines, TB medications, hormonal agents, insulin products, prophylactics, amongst others

Local manufacturing In Kenya

In Kenya, 30% of the value of the pharmaceutical market is produced locally. 80% of that local production is supplied by 10 manufacturers - producing mostly lifestyle and branded generic medicines

Kenyan manufacturers **produce in the final dosage form** (fill and finish) value chain – **importing all APIs**. There is limited R&D in the local market with ~80% of local manufacturers producing branded generics in multiple dosage forms (largely tablets, but including some other dosage forms as well)

Kenyan manufacturers could be cost competitive in tablet manufacture when compared to India - ~3% more expensive when capacity and utilisation are held constant. However, cost competitiveness varies – Kenya is most competitive on branded generics, but not so on unbranded generics, where India has significant scale advantages

Kenya has provided support to **improve local manufacturing maturity over the last 5 years** with targeted support (Essential drug list procurement, pricing preferences for local manufacturers, improving tender process, and market transparency); however, this support still has some improvement opportunities such as expanding the essential drug list, ensuring pricing preference benefits manufacturers, improving processes further (drug registration, payments, publishing market information)

Local manufacturing capacity and standards has continued to expand with some players looking to Europe as their next target market

1. Donors and associations

Executive Summary (2/2)

Opportunities to scale

Local Kenyan manufacturers could have an **addressable market of ~$760mn.** This includes both expansion of production for the local market as well as export, primarily targeting government and private buyers. Donors are deprioritized due to pre-qualification requirements, no pricing preference and sourcing from single large suppliers

Capturing this value requires pursuing 5 opportunities:

- **Import substitution focused on KEMSA procurement** needs for existing manufactured products
  - Opportunity of $50-100mn, 1-2 facilities and 300-600 jobs created. Focussed on manufacturing antibacterials, cardiovascular agents, antiparasitics, hormonal agents, analgesics (e.g. tetracycline, albendazole, etc.)
  - Barriers to unlock are tender process and enforcement, limited scale, lack of policy cohesion and lower standard products
- **Manufacture new medicines** in their final dosage form for KEMSA and the private market
  - Opportunity of $150-200mn, 2-3 facilities and 600-900 jobs created. Focussed on manufacturing suspensions, vials, injectables, immunological agents (e.g. Tramadol, narrow spectrum antibiotics, etc.)
  - Barriers to unlock are insufficient available market information, long drug registration times, low guaranteed demand, and lack of capabilities / skills
- **Expand capacity of existing products for regional export**
  - Opportunity of $250-300mn, 4-5 facilities and 1 200-1500 jobs created. Focussed on manufacturing antibacterials, cardiovascular agents, antiparasitics, hormonal agents, analgesics (e.g. tetracycline, albendazole, etc.)
  - Barriers to unlock are regional harmonisation, stabilised incentives, and pricing competitiveness for exports
- **Improve standards for export of existing products to SRA** countries Private buyers
  - Opportunity is significant with Europe's market size over $250bn. Focussed on manufacturing antibacterials, cardiovascular agents, antiparasitics, hormonal agents, analgesics at a higher regulatory standard
  - Barriers to unlock are limited inspection availability and limited capabilities to produce at SRA standards
- **Manufacture API's for local and regional market**
  - Opportunity $150-200mn, 10-15 facilities and 1 000 – 2000 jobs created. Focused on API manufacture for analgesics and systemic antibacterials
  - Barriers to unlock are lack of industry maturity and limited ability for scale

Manufacturing of pharmaceutical products within East Africa

Market overview

Local manufacturing

Opportunities to scale

Why does localising pharmaceutical manufacturing matter?

To improve public health and strengthen socioeconomic factors

Benefits		Key takeaways
Improved public health	 **Improve self-reliance for sustainable, secure supply**	**Improve availability** for middle-income African countries Continue **production of less profitable pharmaceuticals** of public health importance for Africa **Improve efficiency** and reliability of **healthcare** responsibility to address the disease burden[1]
	 **Address Africa-specific burden and context**	**Potentially stimulate** research for Africa-specific products **Strengthen efficiency in the healthcare administration** Stimulate local production of **newer generation drugs**
	 **Improved regulatory and quality systems**	Enhance government commitment to **reduce delays in product registration** Strengthen the **fight against counterfeit drugs** Strengthen the regulatory body's push for **manufacturers to meet quality for exports**
Strengthened socio-economic factors	 **Support diversified, value-adding socioeconomic growth**	Provide direct semi-skilled **job and skill creation** in a value-adding industry **Reduce trade deficits** in long-term, ease FOREX requirements
	 **Build political goodwill and sovereign security**	Promote **national/continental independence** and build regional harmony
	 **Strengthen local industry technological capabilities**	Provide indirect impacts of **developing a technical industry** (e.g., crowd-in of other scientific industry, other investors etc.)

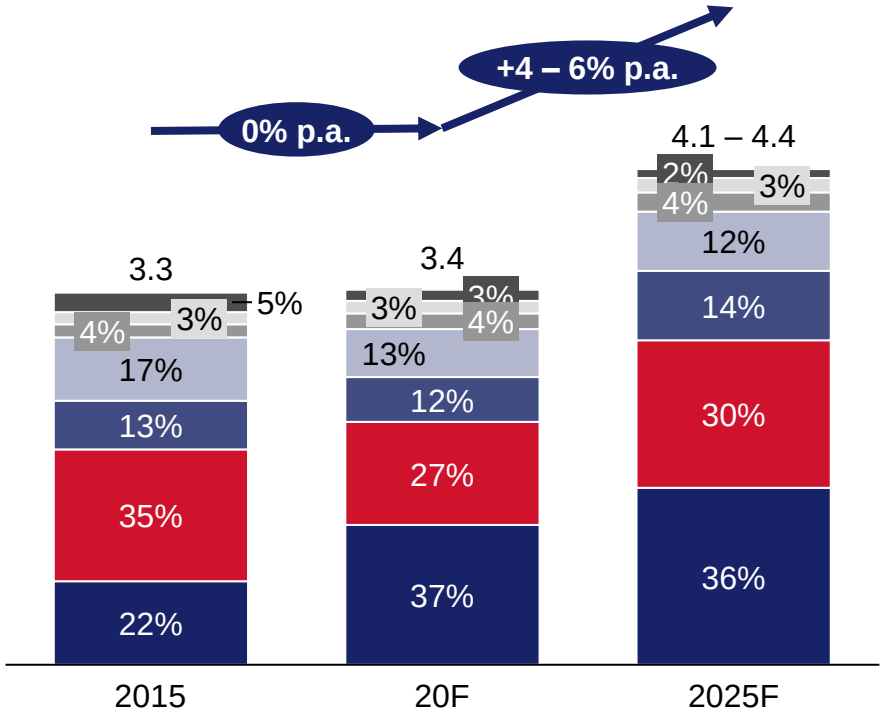
1. Such as a growing disease burden towards Non-communicable diseases

Source: Press scan, expert interviews, local manufacturer interviews, KEMSA, Unlocking the potential of India-Africa collaboration for healthcare innovation report

The East African (EA) pharmaceutical market is a ~USD 3.4 Bn industry expected to grow at 4-6% p.a. until 2025

Pharmaceutical market in East Africa[1,2]

USD billion



The growth in the these markets is driven by

Growing middle income population and consumer spending

Spending on healthcare in East Africa is expected to **increase by 3 – 5%** through 2025 due to the expanding middle income population

In addition, **consumer spending is increasing** e.g., in Rwanda, per capita spending stands at $825, a 12% increase from 2015

Increasing healthcare capacity

Within the past 10 years, **key hospital chains** e.g., Aga Khan Hospital in Tanzania and Kenya and Clinic Africa in Uganda, **have expanded their geographical coverage across the region through satellite clinics** increasing uptake of their services in rural regions

Increasing governmental support

Governments have launched initiatives to support the local pharma industry, e.g., the creation of the **Kenya Pharmaceutical Sector Development Strategy** in partnership with UNIDO[3], and **the prioritization of the pharmaceutical industry** in the Tanzanian 2016 – 2020 development plan

1. Sizing inclusive of the impact of COVID; reduction of CAGR growth forecasted (pre COVID) by 23% in the case of growth returns leading to full recovery (most optimistic scenario) and reduction of CAGR growth forecasted (pre COVID) by 40% in the case of slow long term growth insufficient to deliver full recovery (least optimistic scenario)
2. Exclusive Somalian and South Sudan market given lack of data, inclusive of Malawi (as per client's request)
3. United Nations Industrial Development Organization
4. Significant decline from 2015 to 2020 due to currency depreciation and COVID impact

Source: BMI Research 2020, World Bank, ITC 2015 – 2019, press research, expert interviews

Kenya has the largest pharmaceutical market in East Africa worth ~$ 1.2Bn

Overview of the market[1]

~$1.2Bn	Pharma market size[2]
~$100M	Exports
~70%	Imports, % of pharma market size value
~60%	Generics
37+	# of manufacturers
$1.5	Revenue generated by $1 of CAPEX
7% p.a.	Growth until 2025

Drivers

- **Increasing spend on healthcare** (projected to increase by 3 – 5% through 2025) due to the expanding middle class
- **Increasing healthcare capacity** with key hospital chains expanding their geographic coverage
- **Increasing government support** of local pharma (e.g., Kenya Pharmaceutical Sector Development Strategy)
- **Increased life expectancy** (+5 years between 2000 and 2018) and **population growth** (24% increase between 2010 and 2018)

Key insights

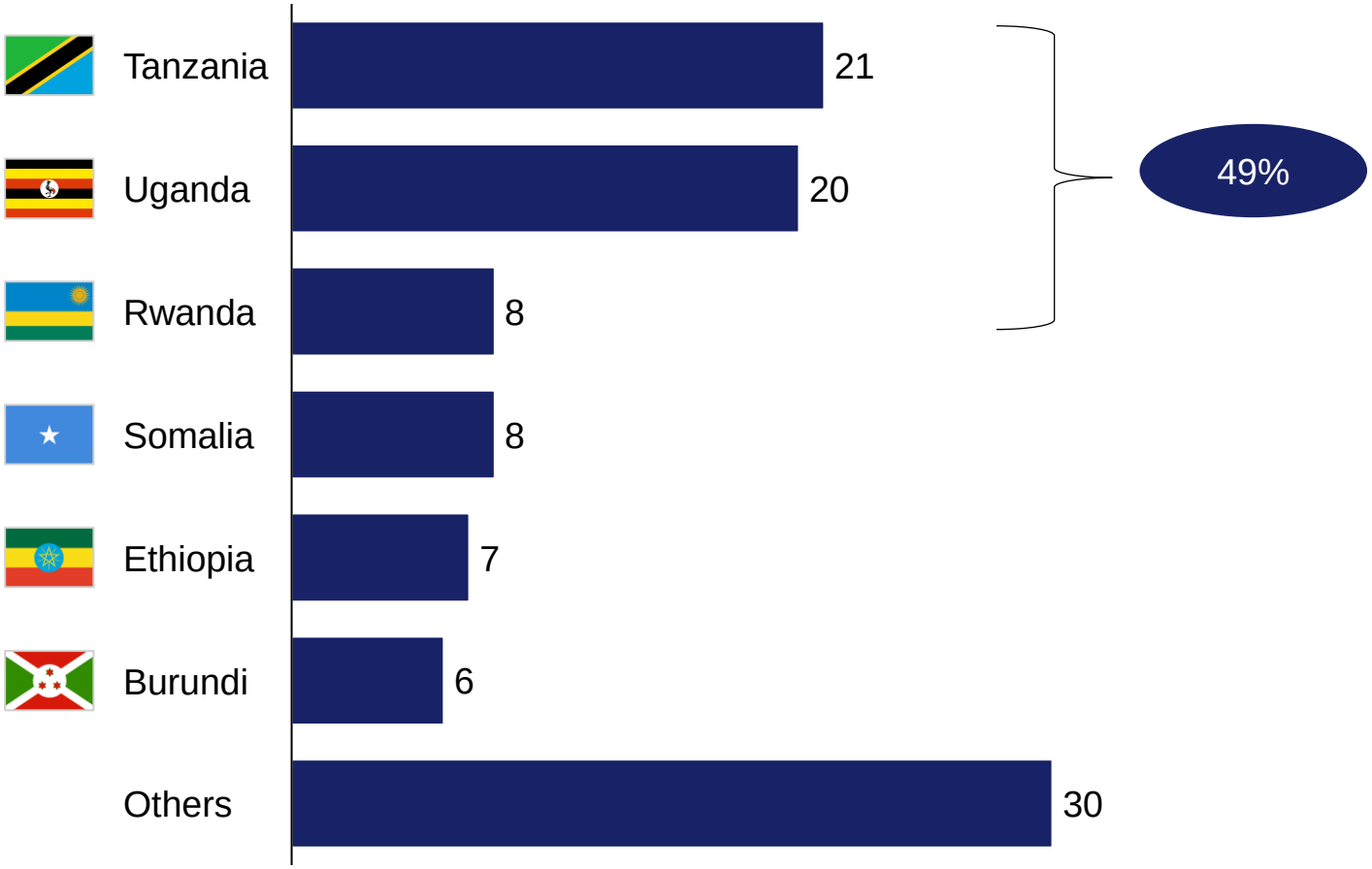
Kenya is a growing market with an opportunity to expand local production

1. Overview of the market in 2019
2. Including donor organisations

Source: Expert interviews, WHO, UNIDO, Team Analysis, KAM

Kenya exports to the broader East Africa region

Kenya's exports of pharmaceutical products (2019), %



1. Only players with local manufacturing presence

Source: BMI Research 2020, World Bank, ITC 2015 – 2019, UNIDO EAC sector analysis press search

Kenya's strength in pharma exports is driven by:

The **advancement and development of its local pharma industry** which currently boasts of ~35 international and domestic players[1]

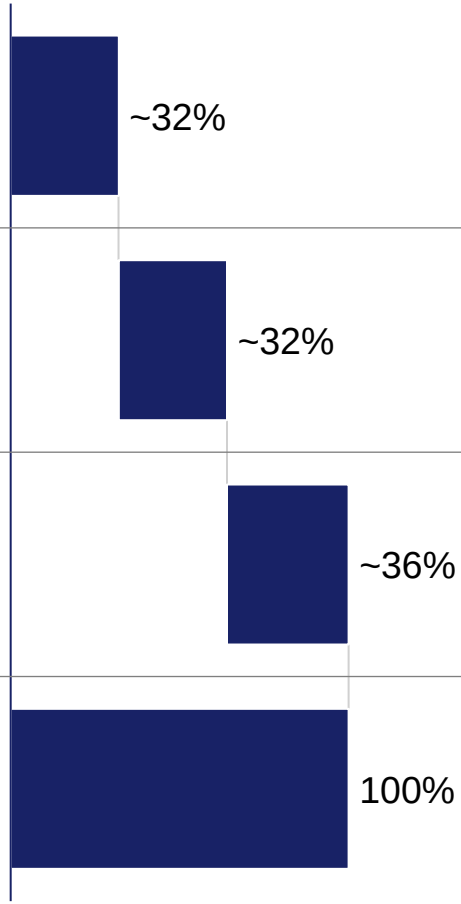
The **well developed distributor network** in the region that acts as a natural advantage for the manufacturers

Lower scale of manufacturing in neighboring countries making the respective countries incapable of satisfying local demand

Tanzania, Uganda and Rwanda represent ~50% of Kenya's export market – Ethiopia is under penetrated

Public and Social sectors are responsible for ~65% of procurement, with KEMSA as the largest buyer

Kenya market sales split by major category of buyer



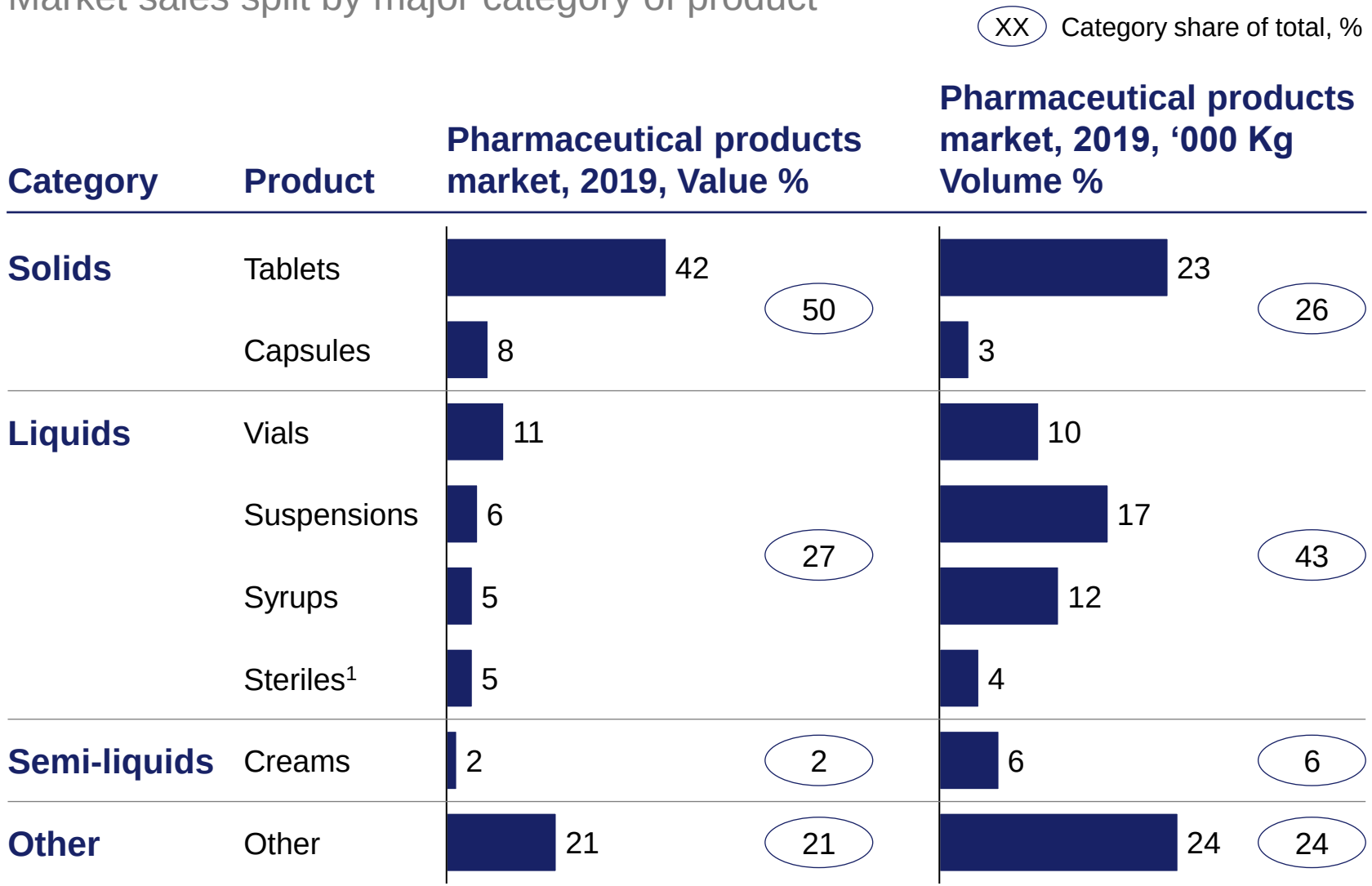
Estimated sales value %	Imports Estimate %	Imported Medicines	Buyers and payers	Procurement methodology
Public sector	~40%	**Oncology products, Insulin, Cardiovascular system**	**Buyer**: KEMSA **Payer**: Revolving drug fund (National government)	Open public tenders where any manufacturer can compete
Social sector	~100%	**Antiretrovirals, Vaccines Antimalarials, Family planning, Tuberculosis drugs**	**Buyer**: KEMSA and MEDS[1] **Payer**: KCCB[2], CHAK[3], and Donors (e.g. Global Fund, USAID)	Closed public tenders from a list of pre-qualified manufacturers
Private	~70%	**All types**	**Buyer**: Private hospitals, distributors **Payer**: Direct consumers (out of pocket), Medicaid schemes	Public tenders Private contracts
Total market	~70%			

1. Mission for Essential Drugs and Supplies
2. Kenya Conference of Catholic Bishops
3. Christian Health Association of Kenya

Source: KEMSA interviews, Manufacturer interviews, Press research, BMI 2020 research, WHO, expert interviews

Solids and liquids are ~75% of the value and ~70% of the volume of Kenya's market

Market sales split by major category of product



1. These are injectables

Source: IQVIA

Key observations

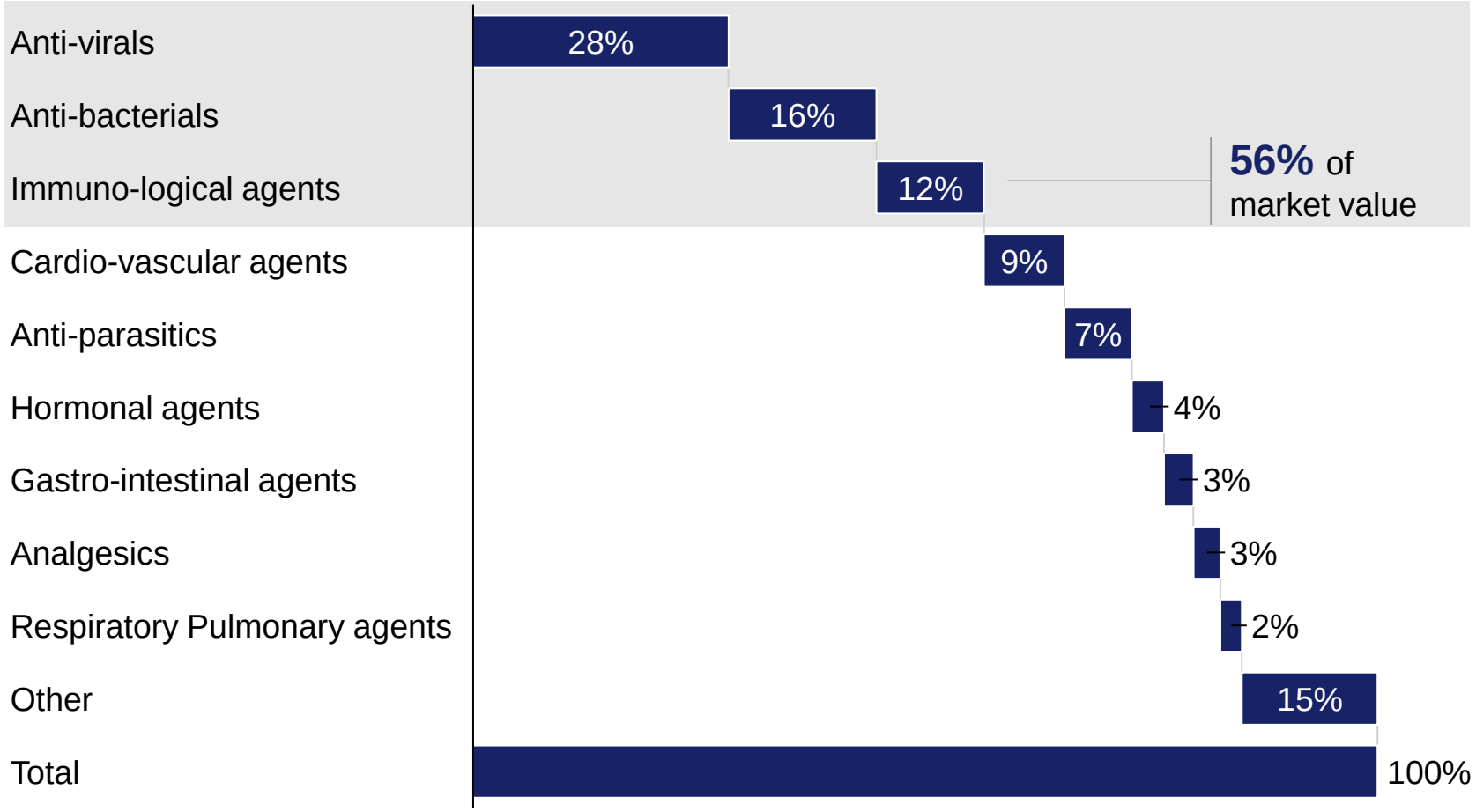
Solids and liquids are the two significant product categories in terms of value and volume

- **Solids have the largest absolute value** with~50% of the market value followed by liquids at >25%
- **Liquids have the highest volumes,** comprising >40% of the total, followed by the solids, which represent ~25% of the volumes of which 23% are tablets

Antivirals, anti-bacterials and immunological agents generate over 55% of market value in Kenya

Market sales split by major product

Top 10 products by market value, % of market value



Source: Pharmacy and Poisons Board

The top 10 product categories account **for 85% of the total Kenyan market** driven primarily by antivirals, anti-bacterials and immunological agents

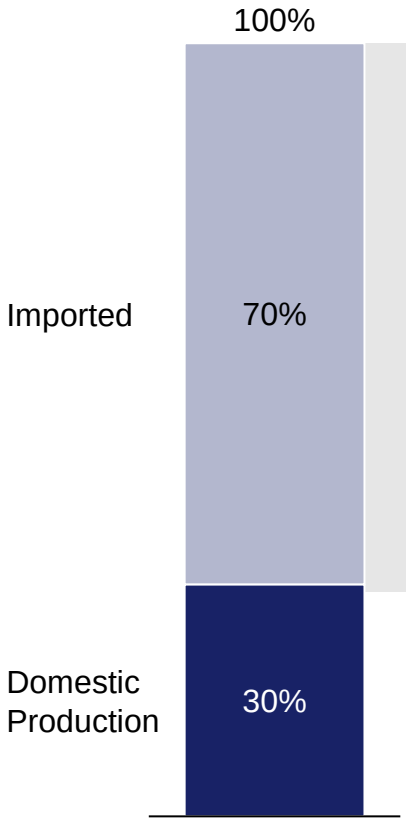
70% of the pharmaceutical market value is served by imports, of which India is the largest import partner

Pharmaceutical products imports[1], top 10 import partners

NOT EXHAUSTIVE

X% Imports in %

Total market split, %[2]



	2019, Trade Value ($mn FOB)		2019, Volume (thousand Kg)	
Total	553	100%	30.865	100%
India	249	45%	13.122	43%
Germany	38	7%	520	2%
USA	34	6%	95	0%
China	33	6%	6.382	21%
United Kingdom	31	6%	814	3%
Belgium	31	6%	266	1%
France	25	5%	619	2%
Pakistan	12	2%	531	2%
Denmark	11	2%	192	1%
Italy	10	2%	379	1%
Other	79	11%	7.944	26%

Key observations

India is the largest import partner by value and volume

China has high volumes and low value – likely importing low value products

India is primarily importing

- Anti-virals
- Vaccines
- Finished antibiotics
- Tuberculosis (TB) medications
- Hormonal agents
- Insulin and other diabetics
- Prophylactics
- Analgesics
- Other unbranded generics

1. Products procured by global donors not captured in the analysis
2. Result of expert interviews

Source: Comtrade; Interviews with local manufacturers

Overview of the pharmaceutical landscape

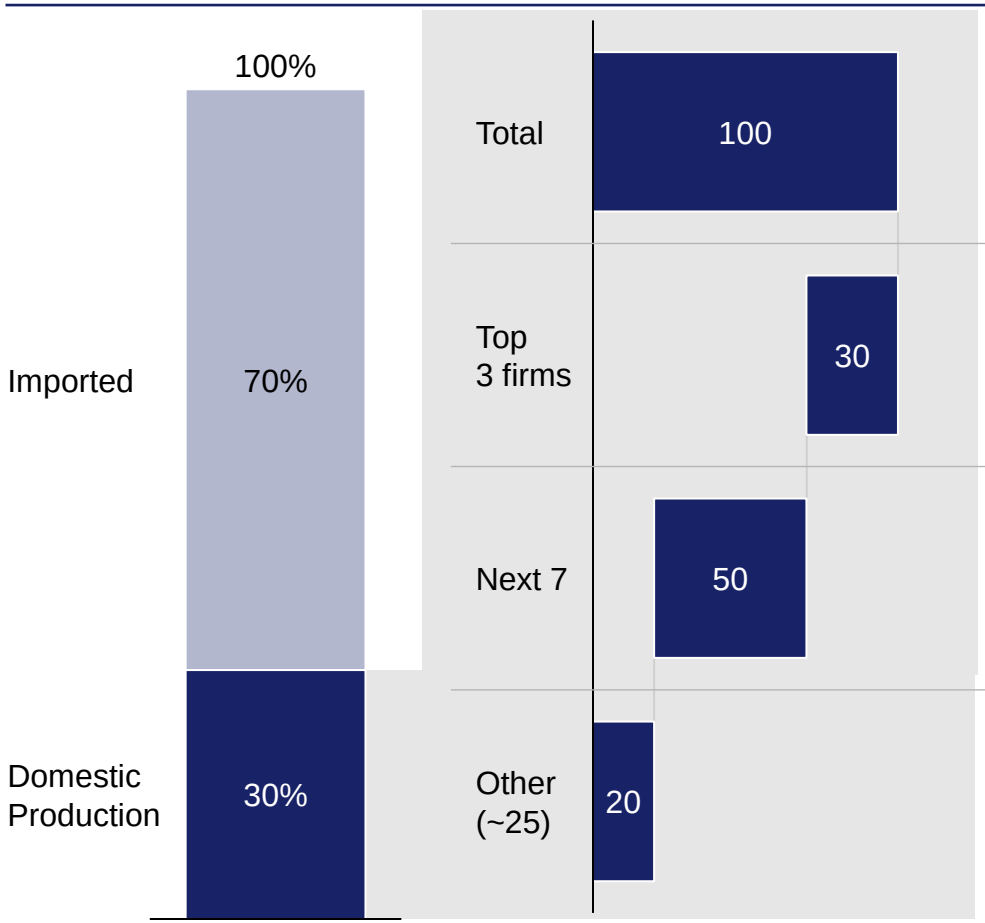
Market overview

Local manufacturing

Opportunities to scale

The top 10 manufacturers capture ~80% of the local production

Market share of local production by value (%)



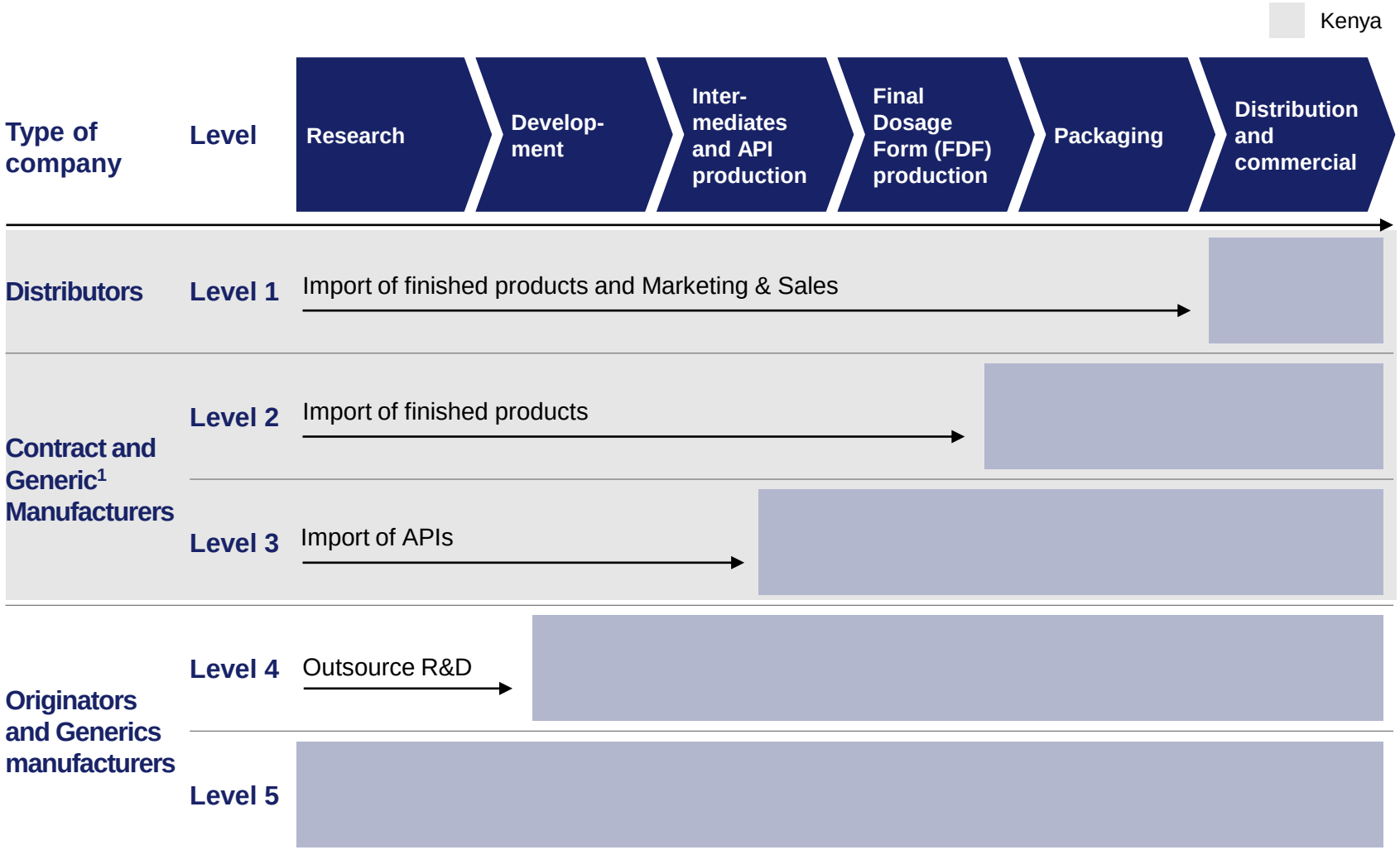
	Local producers	Type of drugs manufactured	Product category
Top 3 firms	GlaxoSmithKline (GSK)[1] Dawa Cosmos	GSK mostly consumer health Dawa mostly branded generics and lifestyle medicines Cosmos mostly lifestyle	Solids, Liquids, and creams
Next 7	Laboratory & Allied, Universal Corporation, Regal Pharmaceuticals, Biodeal, Elys Chemical Industries, Biopharma, Beta Healthcare International	Mostly branded generics with a mix of consumer health and lifestyle medicines	Solids, Liquids, and creams
Other (~25)	Multiple others	Almost completely branded generics	Mostly solids

1. Considered to be top 3 local player but would import some products from other facilities

Source: IFC Pharmaceutical Sector Diagnostic Report 2020, Interviews with Manufacturers, Dun & Bradstreet

Local manufacturers focus on final dosage form production - importing all APIs

5 levels of pharmaceutical manufacturing



1. Generics can be unbranded or branded
2. Active Pharmaceutical Ingredients

Source: 2nd EAC Regional Pharmaceutical Manufacturing Plan of Action 2017–2027; Kenya Pharmaceutical Industry Diagnostic Report 2020

Key observations

No APIs[2] are locally manufactured

The majority of the players in the Kenyan pharmaceutical sector are **predominantly producing finished pharmaceutical products** and distribution

Pharmaceutical value creation progresses from the simple importation of finished a product (Level 1) to a sophisticated, research-based pharmaceutical industry (Level 5)

Kenya mostly produces branded generics

Type of company	Description	Est. share of local market production	Example companies
Contract Manufacturers (CMO)	Contracted by a pharma company to provide the materials and labor to manufacture drug products which are then owned and paid for by the client (pharma company).	<5%	Small number of micro players (e.g. Skylight Limited)
Branded generics manufacturer (IP Owner[2])	Manufacture products which no longer hold patent protection and are marketed with their own brands (branded generics)	~80%	Cosmos Limited, Dawa, Biodeal, Laboratory and Allied, Elys, BioPharma, Universal, Regal Pharmaceuticals
Originator	Manufacture their own brands with APIs internally developed	~15%	GSK[1]

1. GSK is an originator but development is not done within Kenya
2. Intellectual Property owner - these manufacturers own the branding of the medicine they manufacture

Source: Interviews with local manufacturers; IFC Kenya Pharmaceutical Industry Diagnostic Report 2020

Local players focus on branded generics

Kenya can be cost competitive for branded generics but struggles to be cost competitive for unbranded generics - most local companies produce branded generics

Local manufacturers produce

- **Branded generics** and compete in the same market segments with similar product portfolios
- **Multiple dosage forms**, such as plain tablets and capsules, while some firms diversify by producing syrups, suspensions, and creams (a fast-growing segment)

Over **1/2 are producing anti-infectives**

Only three firms produce steriles, that require technologically complex processes and stringent quality control standards

Kenya could be cost competitive versus imports on the manufacture of tablets

Context

The analysis compares the competitiveness of the price of tablet pharmaceuticals imported from India to those manufactured in Kenya

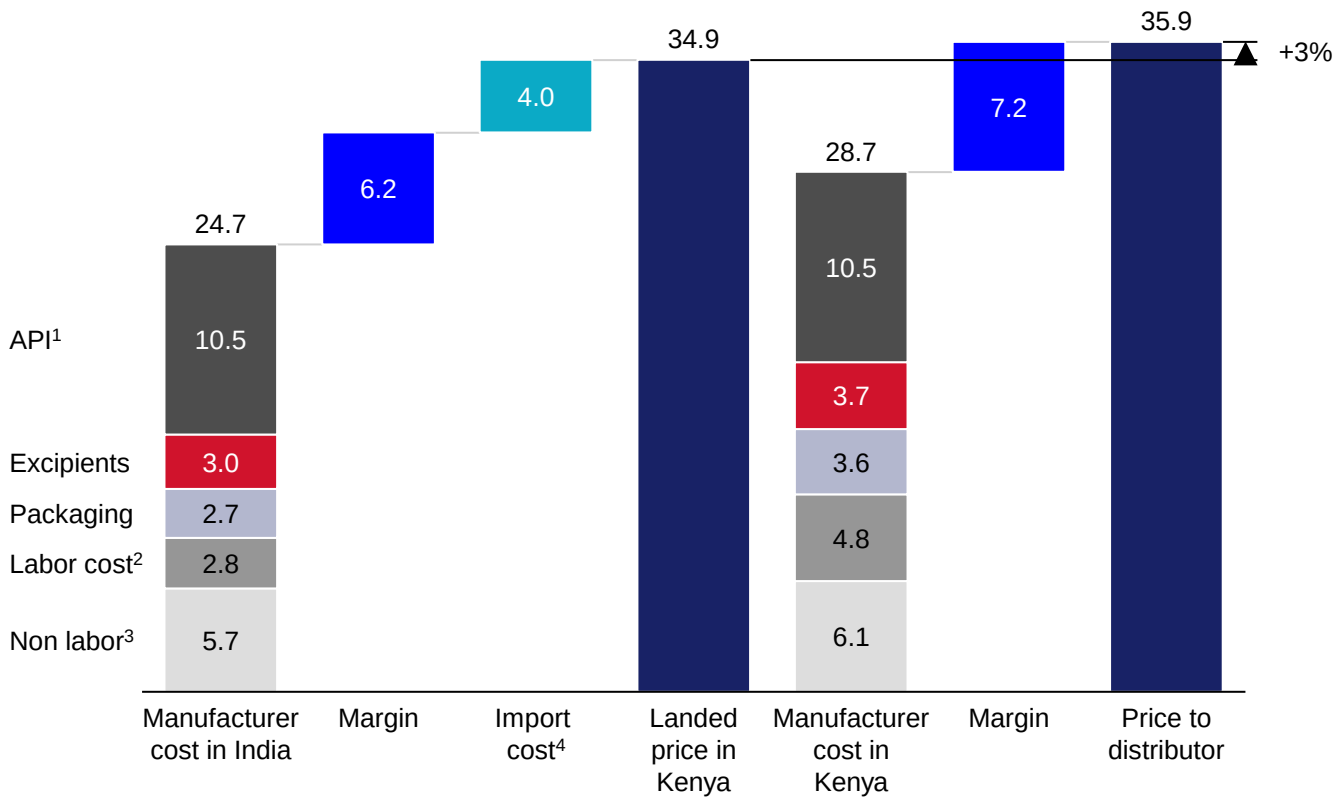
In the full-import model, benchmark median costs from India were considered

In the absence of data for Kenya the median of the costs of a benchmark sample of developing countries[6] was considered in the mixed model

The median size of a site considered was 3 bn tablets per year and utilization is held constant, assuming the utilization of 40%

Full-import model (from India)
$/1,000 tablets (solids)[5]

Mixed model (API import + Kenya formulation)
$/1,000 tablets (solids)



Key insights

Local tablet manufacturing can be cost competitive vs. imports from India when capacity and utilization are held constant

- Kenya is 3% more expensive to manufacture than India
- KEMSA offers a pricing preference of 15%

Economies of scale are key to competing with India on cost - local manufacturing may be in an even better position due to its high utilization (60-80%)

1. Active pharmaceutical ingredient
2. Includes direct labor and support and overhead costs
3. Incudes utilities, consumables, other non-labor related cost components and annual depreciation
4. Includes freight: 13%; duties: 0%; and value-added tax: 0% of API value
5. Based on a sample of 57 solids sites in developing countries: Brazil, China, Egypt, India, Jordan, Morocco, Pakistan, South Africa, Thailand, Turkey

Note: This analysis is for solid pharmaceuticals; economics for other drugs may vary

Source: McKinsey PMP Practise, expert interviews, interviews with local manufacturers

Kenya has worked hard over the last five years to improve their local environment…

Developed an essential drug list

KEMSA developed an essential drug list (“master roll”) of >125 items that must be procured locally by all public agencies

Set local pricing preferences

There is a 15% pricing preference for locally manufactured goods

Tax incentives/deductions have been implemented for facility investments (e.g. investment cost has a tax deduction)

Prioritised drug registration for local manufacturers

PPB gives local manufacturers a cheaper and faster registration process for new drug manufacturing

Improved tender process

KEMSA historically paid in bulk at the end of the contract but have improved their payment cycles thereby aiding cash flows (ranges from 90-210 days)

Public accountability of tender outcomes

KEMSA provides the market with the tender results increasing procurement transparency

… but could further support localisation

Expand the essential drug list

Identify additional medicines over the next few years that local manufacturers can be self-sufficient in and grow the master roll

Improve pricing preferences

10% of the pricing preference goes to the distributor resulting in only a 5% gain for manufacturers – this preference could be assessed so more of the pricing belongs to majority owned local manufacturers

Implement faster registration processes

Registration can still take over a year – this process could be improved to weeks

Improving tender payment process

Paying local manufacturers and distributors within 90 days and issuing letters of credit

Publish market information

KEMSA should publish their market consumption and purchase data publicly enabling manufacturers to better understand which medicines are in demand

Source: Interviews with local manufacturers; IFC Kenya Pharmaceutical Industry Diagnostic Report 2020

Local manufacturers are still expanding - focuses on exporting current products and installing capacity for new products

Manufacturers are looking to expand…

Most local manufacturers are at 60-80% capacity utilisation

Several are looking to expand manufacturing, focusing on the following areas:

- **Improve the standards** of the current product lines to export regionally and globally (e.g. Europe)
- **Install fill and finish capacity to replace imported products** needed for the regional market (e.g. Oncology, hormones, insulin, vaccines)

…and feel there are several positive characteristics in Kenya to allow expansion

Strong access to finance

"I get a call from a private equity firm wanting to invest every month"

Cost competitiveness

"For some products imports have even stopped because of lack of competitiveness – Kenya can manufacture the product 15% cheaper than the import"

Quality standards

"We can be competitive to export to Europe as we have ability to manufacture high quality at low cost"

Easy access to raw materials

"APIs and excipients[1] can get here cheaper than in India due to export rebates"

1. Raw material ingredient that stabilises the API

Source: Interviews with Manufacturers

Overview of the pharmaceutical landscape

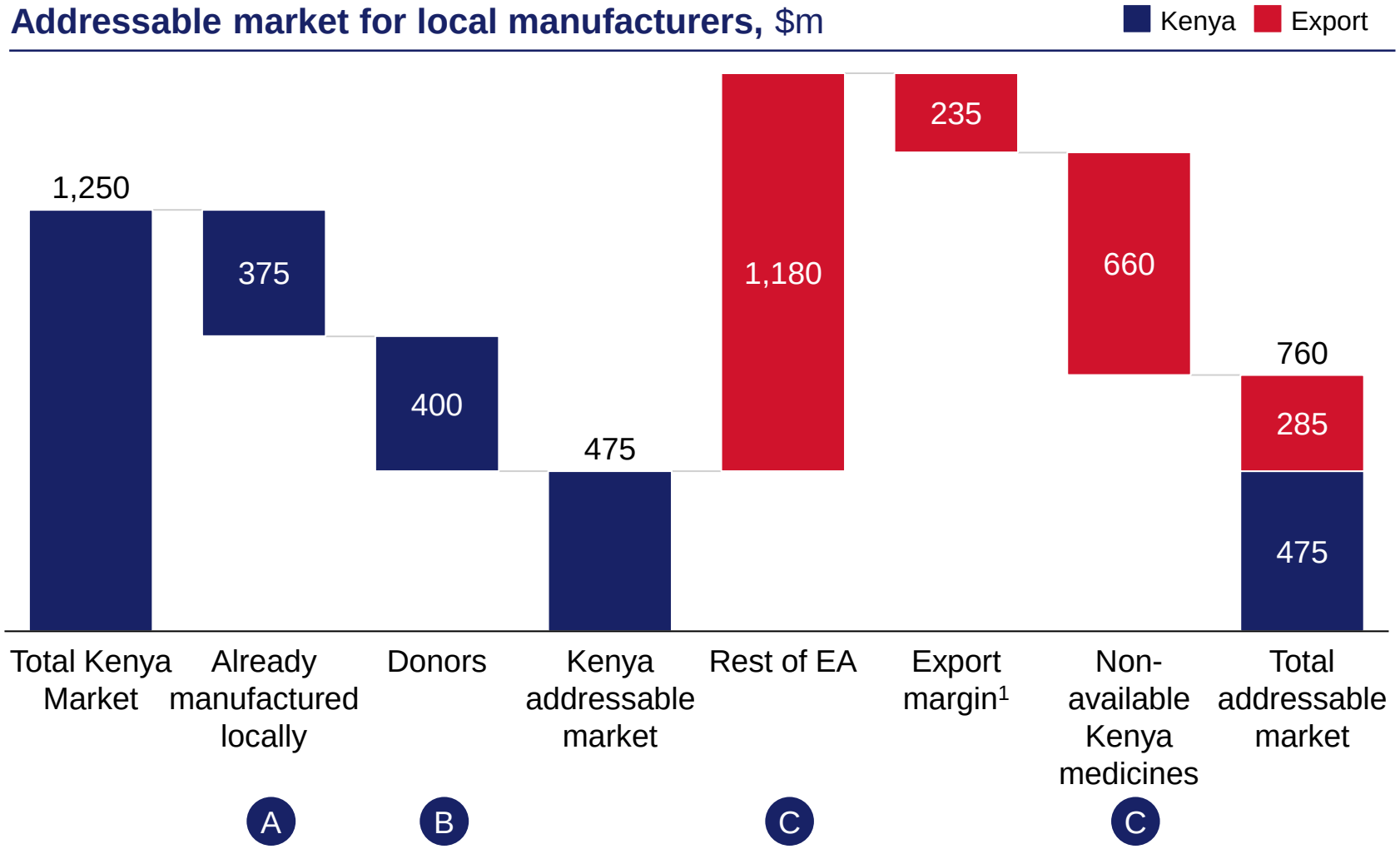
Market overview

Local manufacturing

Opportunities to scale

Local Kenyan manufacturers could have a total addressable market of ~$760mn

Addressable market for local manufacturers, $m



1. Exporting distributors average price margin is 20% - this will remove manufacturing revenue potential

Source: Comtrade; Interviews with local manufacturers, BMI Research 2020, World Bank, ITC 2015 – 2019, press research, expert interviews

Key observations

Kenya's addressable market is excluding

- Products already manufactured locally
- Donor procurement

Total addressable market consists of rest of East Africa's total market excluding

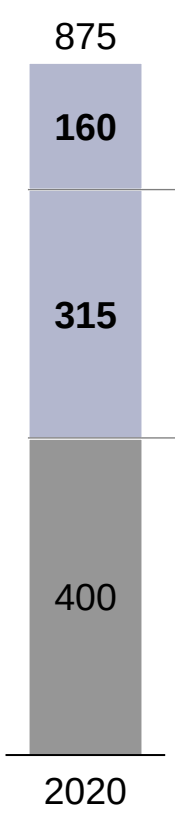
- Ethiopia due to forex constraints and low local will to export there
- Distributor margin of ~20%
- 70% of the market - assumes similar market dynamics to Kenya that can be supplied

A. Excluding donors, there is a ~$475m addressable market for import substitution

Opportunity focus Low High

Kenya pharma market breakdown of import buyers, $m

Current ability to serve



KEMSA

Pricing preference will assist local ability to serve

Preference to support local manufacturing

Private

Largely buying unbranded generics that Kenya is not cost competitive in

Buying branded generics that are incentivised by the originator

Donors

Donors procure their medicines globally from large, pre-qualified manufacturers

Kenyan manufacturers are unlikely to win global contracts[1]

- Require WHO/FDA standards
- Insufficient capacity to match full demand required for tenders

Key insights

Tenders for the KEMSA are more accessible to local manufacturers

- 15% price preference for local manufacturers (shared amongst distributors who take 10%)
- No required pre-qualifications for medicines
- Import ~40% of their procurement

Tenders for the private sector are driven by market dynamics

- No pricing preference
- Private sector imports ~70% of their procurement

1. Majority of vaccines are purchased by donors (e.g. Gavi, UNICEF) and these are considered in another scope of work “What will it take to expand vaccine manufacturing in Africa”

Source: Comtrade; Interviews with local manufacturers

B. Local manufacturers are not able to participate in donor tenders due to lack of pre-qualifications

Tender	Frequency	Considerations	Main suppliers	Contract nature
Public sector through Revolving Drug Fund (RDF)	**Every 2 years** with call off quantities as needed Ad-hoc tenders in case of standalone procurement of new products is required	**No prequalification** required **15% price preference** for localised entities **GMP standards** are sufficient Controlled mainly through **post market surveillance**	International manufacturers Local manufacturers	Multiple contractors not yet in place Challenges in the forecasting due to the 2 year planning
Social sector through Donors (e.g. Global Fund, USAID, UNFPA, Gavi)	**Tender contracts every 1-2 years** Volumes are ordered monthly through global distributor agency	**Pre-qualification required** per product Products supplied must be **WHO, FDA or EMA approved** **No price preference** in place	International Manufacturers Local manufacturers pre-qualified • Cosmos • Universal Corporation	Global or regional contracts Single suppliers usually awarded (not typically sub-scale procurement)

Almost **no Donor contracts are won by local manufacturers**

Limited pre-qualified products (Two local manufacturers with limited pre-qualified products)

Lack of price competitiveness

Limited scale to serve single large contracts for region / global distribution

> **"Their pre-qualification criteria excludes us from even participating"** – *large local manufacturer on donors*

Source: Interviews with KEMSA, Interview with Local Manufacturers

B. Donor groups focus on specific medicines and are most concerned about health risks

It is unlikely for Kenya to supply donor tenders in the near term without agreed commitments from donors, government, and local manufacturers

Donor	Main medicines procured
Gavi	Routine immunisations[2]
USAID	HIV / AID Family planning[3]
Global Fund	Tuberculosis Malaria
UNFPA[1]	Family planning[3]

Primary considerations for procurement

Health risk

Medicines must be WHO pre-qualified or equivalent to ensure the dosage is the most effective for the patient

Supply security

Sufficient capacity from single suppliers

Reliable power supply

Sufficient foreign exchange reserves

Pricing

Donors purchase at the lowest price available in order to serve more people with limited resources

What it could take to provide donors

Donor organisations, Government, and manufacturers would need to **work together and plan supply** and their commitments

Manufacturing lines would need to be **WHO pre-qualified**

Local manufacturers would need to be **price competitive for generic medicines**

> **"You cannot beat their price – at best you can match it"** – *Expert on donor procurement from India and China*

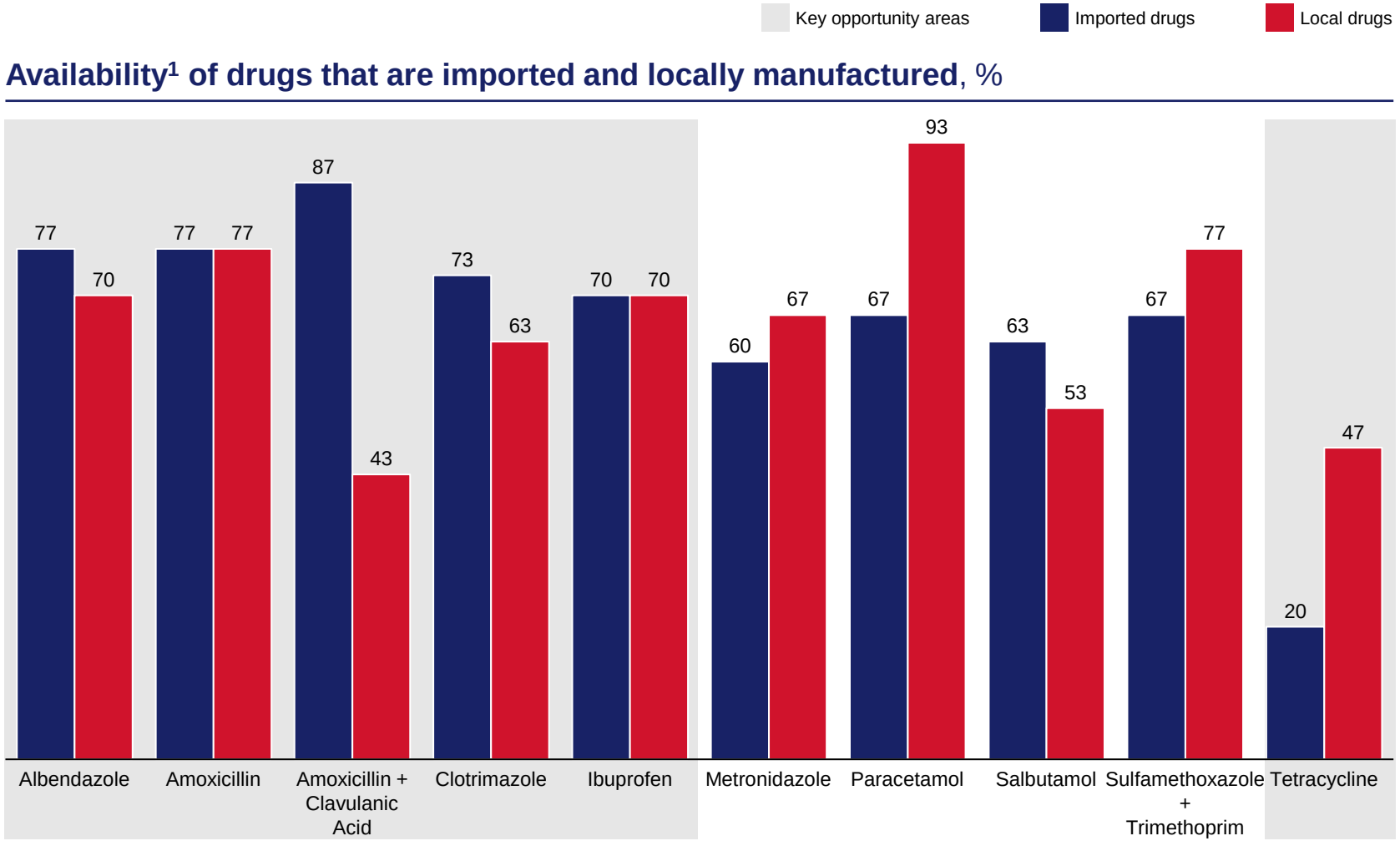
1. The United Nations Population Fund
2. Vaccines (and are usually 80% funded by Gavi depending on the country's development)
3. Contraceptives and other similar items (condoms, injectables, oral birth control, IUD implants, etc.)

Source: Press scan, Expert interview

B. Local manufacturers could leverage existing capabilities to substitute imported drugs

NOT EXHAUSTIVE

Availability[1] of drugs that are imported and locally manufactured, %



1. Availability is relative to the market demand (>100% shows the drug has additional supply available)

Source: IFC Kenya Pharmaceutical Industry Diagnostic Report 2020

Key insights

Almost all of these drugs have **excess availability** – tetracycline has low availability

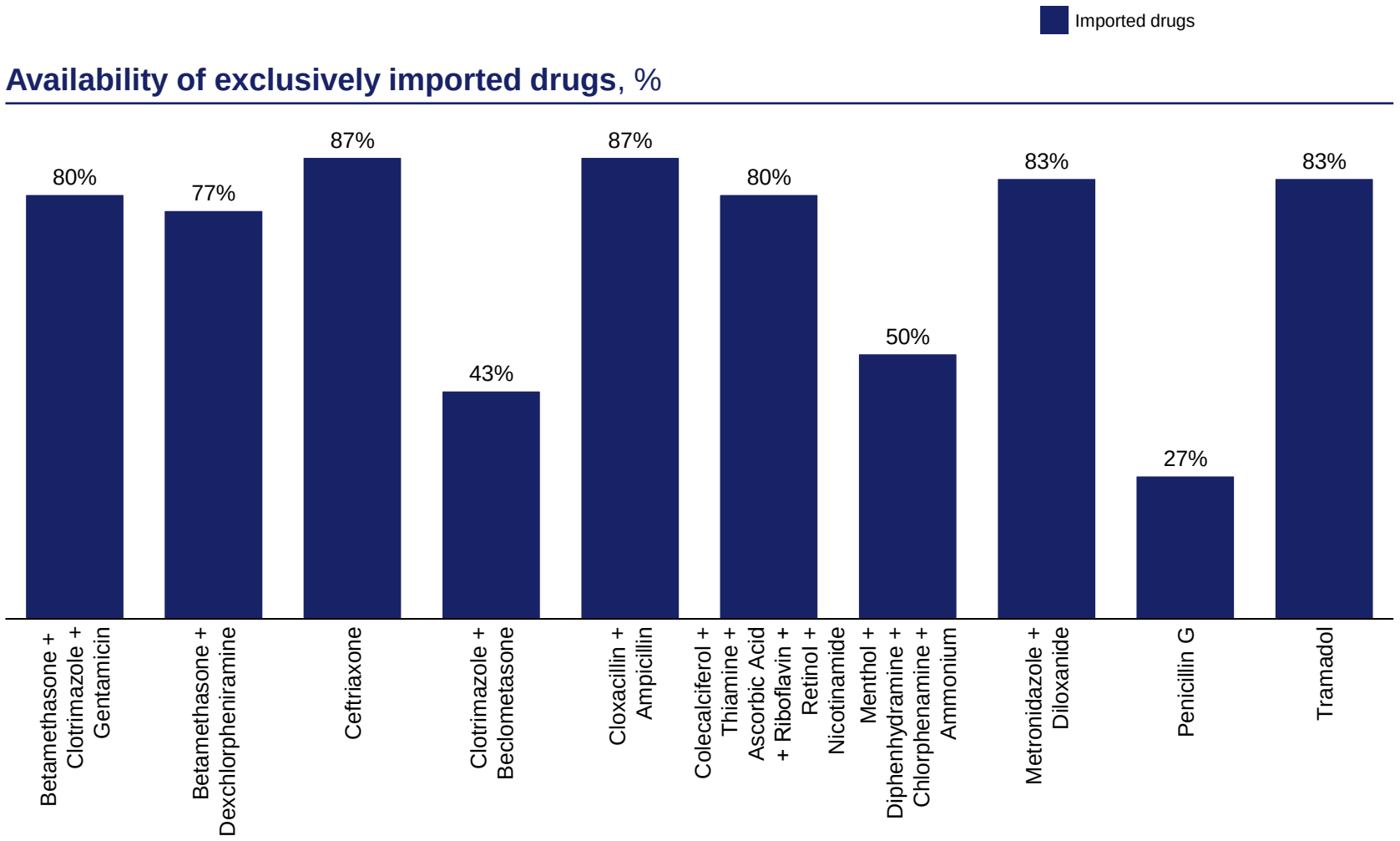
Drugs that are already **manufactured locally and are still being over-imported** or with large **availability deficiencies** showcase opportunities for scale

- Albendazole (de-worming tablet)
- Amoxicillin +Clavulanic Acid (bacterial antiobiotic)
- Clotrimazole (antifungal cream)
- Ibuprofen (non-steroidal anti-inflammatory)
- Tetracycline (antiobiotic)

B. For new drugs, Kenya can develop the capacity and capabilities to supply these to the market

NOT EXHAUSTIVE

Availability of exclusively imported drugs, %



Source: IFC Kenya Pharmaceutical Industry Diagnostic Report 2020

Key insights

Local pharmaceutical manufacturers should investigate **newly manufacturing these exclusively imported** drugs

Drugs available for substitution

- Ceftriaxone (antibiotic)
- Cloxacillin +Ampicillin (antibiotic)
- Metronidazole +Diloxanide (gastric intestinal treatment)
- Tramadol (Opioid pain med)

Lower availability drugs being imported – showing a gap in supply are:

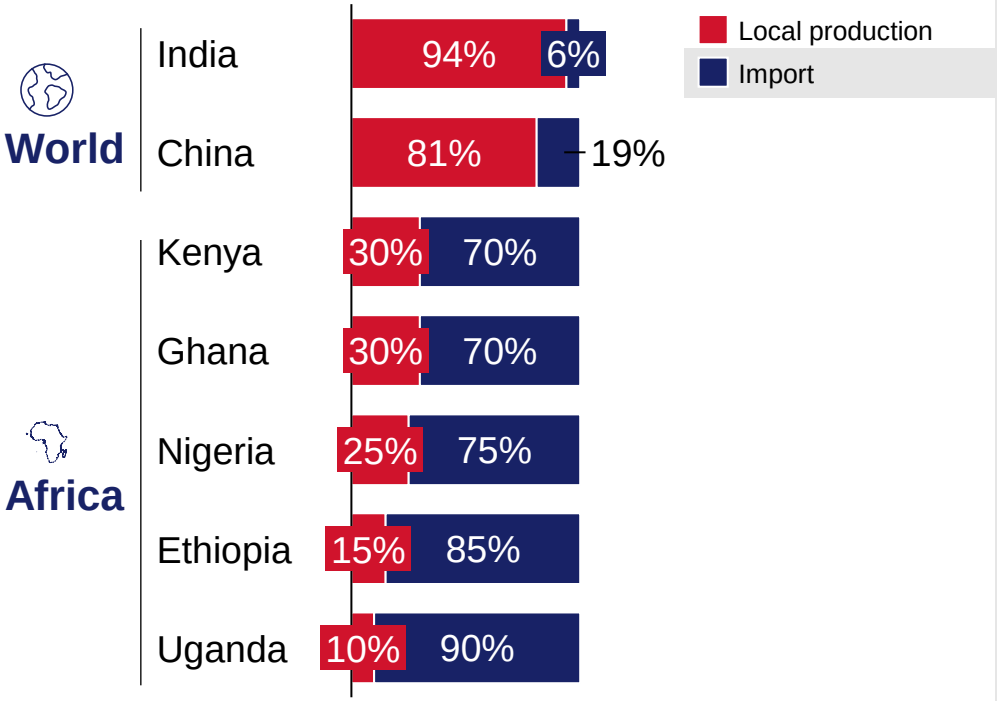
- Penicillin G (narrow spectrum antibiotic)
- Clotrimazole +Beclomethasone (fungal cream)
- Menthol +Diphenhydramine +Chlorphenamine +Ammonium (cough and arthritis syrup)

C. As Kenya is a is a relatively strong EA manufacturer with ~30% of their market localised…

Other EA countries locally manufacture less products relative to Kenya

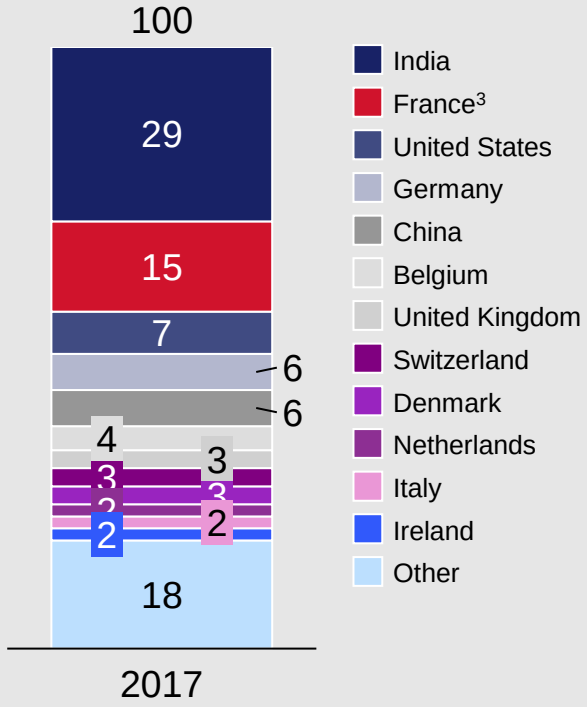
Country dependence on pharma imports

Estimate (2017)[1]



Pharmaceutical imports: origination country

% of pharma market by value[2]



1. PMA of Ghana members (2017), EIC (2016) and National Strategy and Plan of Action for Pharmaceutical Manufacturing in Ethiopia (2015), FEAPM (2018), UNIDO (2011), Kenya BMI report (2018)
2. Based on UN Comtrade data for pharmaceutical products; includes codes 300210, 300220, 300290, 300310, 300320, 300331, 300339, 300340, 300390, 300410, 300420, 300431, 300432, 300439, 300440, 300450, 300490 only, as others do not represent pharmaceutical outputs
3. France's market is significantly higher than other EU countries because its largest importer (Laborex) consolidates all imports to Francophone Africa in France before shipping them to the countries.

Source: Government Action plans, Comtrade, UNIDO, Kenya BMI report (2018)

Key insights

India and china are self sufficient in almost all pharmaceuticals - both >80% local production

Kenya and Ghana are the most self sufficient in the EA region

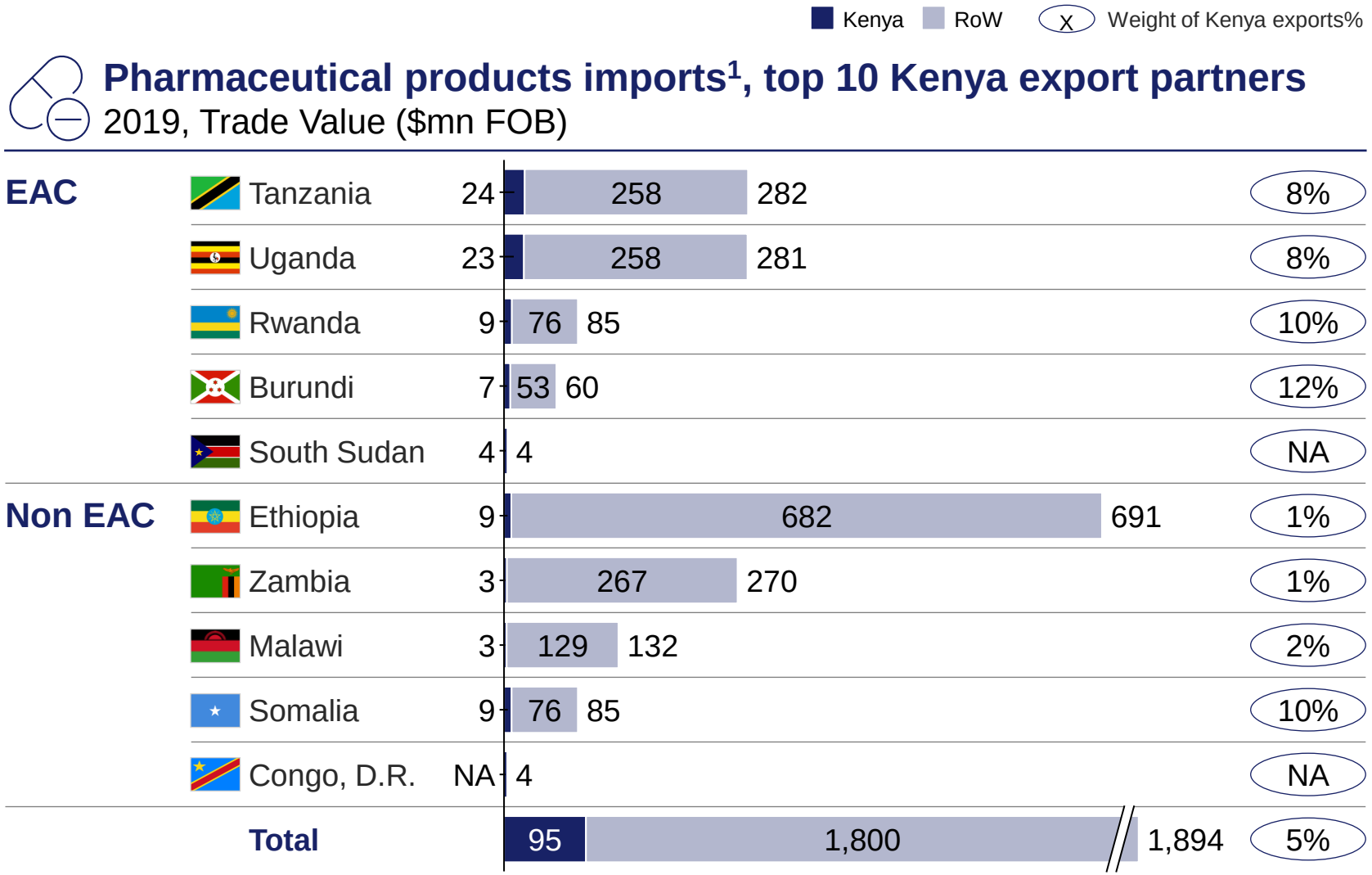
- Kenya localised 30% of the market
- Opportunity to export to neighboring countries with existing products
- Expand local manufacturing capacity subsequently improving self sufficiency

"We are viewed as a foreign country just like India" – *large local manufacturer on exporting to the region*

C. …there are opportunities for Kenya to scale exports to East Africa

Pharmaceutical products imports[1], top 10 Kenya export partners

2019, Trade Value ($mn FOB)



1. Products procured by global donors not captured in the analysis – total EA value is $2.1bn

Source: IQVIA, Comtrade

Key observations

The are considerable opportunities for Kenya to increase exports to neighboring EA countries

- Kenya is generally underpenetrated in the region
- Kenya can leverage existing strong export relations to Tanzania, Uganda and further bolster volumes
- Ethiopia has limited opportunities due to foreign exchange access

5 opportunities were identified to scale pharmaceuticals manufacturing in Kenya and improve local supply security

	Opportunity description	Geography	Product	Size of opportunity	Priority for supply security
Short term (5 years)	1 Import substitution focused on KEMSA procurement needs for existing manufactured products	**Existing geography**	**Existing products**	$50-100 m	✓
	2 Manufacture new medicines in their final dosage form[1] for KEMSA and the private market	**Existing geography**	**New products**	$150-200 m	✓
	3 Expand capacity of existing products for regional export	**New geography**	**Existing product**	$250-300 m	✗
	4 Improve standards for export of existing products to SRA[2] countries Private buyers	**New geography**	**Existing product at higher standards**	Significant opportunity	✗
Long term (5 years+)	5 Manufacture API's for local and regional market	**Existing geography**	**New value chain**	$150-200 m	✓

1. Final dosage forms are products that import the API and manufactured locally as a "fill and finish"
2. Stringent Regulatory Authorities (SRAs)

1. 1-2 additional factories would be required to substitute KEMSA imports of simple products creating 300-600 jobs

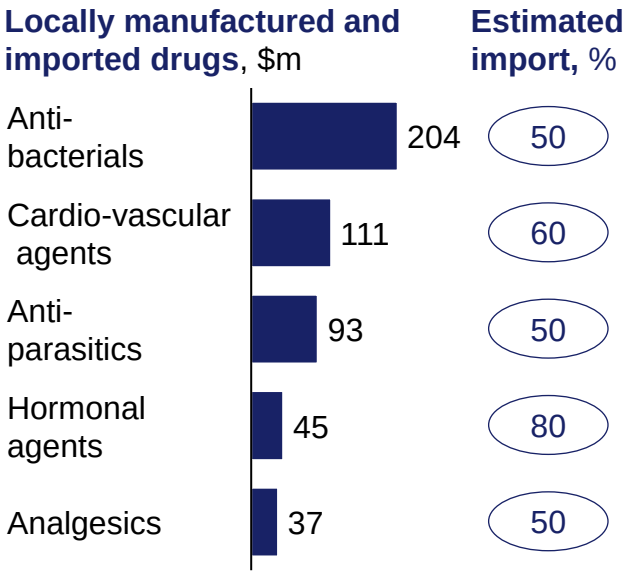
Import substitution focused on KEMSA procurement needs for existing manufactured products

PRELIMINARY DRAFT

Background of the opportunity

Public sector imports a significant number of products manufactured

These **imports consist of products which are being manufactured locally** (ranging 50-80% imported) including:



X32%

Procured by KEMSA

Potential facilities and impact[1]

1-2

new facilities

Could be developed to support the import substitution of simple products for KEMSA

300-600

jobs created

1. Assumptions: Single facility generates $60m revenue and creates 300 jobs (this was assessed off the size of a large facility in Kenya)
2. These impact estimates would need to overlayed with current interest among local manufacturers or potential new entrants

Source: Interviews with Manufacturers, IFC Kenya Pharmaceutical Industry Diagnostic Report 2020

1. There are four main barriers that may need to be unlocked to improve local capacity for existing manufactured products

Import substitution focused on KEMSA procurement needs for existing manufactured products

PRELIMINARY DRAFT

Main Barriers	Potential unlocks	Stakeholders involved	What we heard
Tender process and enforcement • Ensure the local manufacturer is given preference over local importers • Long payment terms weaken cashflows of local manufacturers making scale and investment harder	• Ensure **pricing preference supports local manufacturing** irrespective of the local distributor ownership • **Improve tender payment terms** (e.g. letters of credit, upfront proportion of payment) to allow smaller manufacturers to compete • **Publish** social sector **market information** annually	• KEMSA	"Consumption data is hard to get – **you do not know what the budget will be**"
• **Limited scale to compete with India** making it hard to compete with price	• Promote **aggregate supply** • Provide **grants/incentives** to increase investment in capacity to meet scale • **Strengthen offtake agreements** for local manufacturers	• MoITED • National Treasury	"I have a fear of investing further in capacity - I **do not know if the capacity I invest in will be purchased**"
Lack of government policy cohesion • Different government arms have set different goals resulting in limited communication when determining policy (e.g. aim to increase facility scale but delay the investment tax deduction to 3 years)	**Align Government towards a single goal of localizing manufacturing through scale** • Create the enabling environment to encourage local manufacturing (e.g. pricing and investment incentives, support, etc.) • Stabilise cohesive policies across GoK	• National Treasury • Ministry of Health • MoITED	"**Regulations and rules can change quickly** and this negatively affects cashflow planning – MoITED does one thing and Treasury another"
Lower standard compliance products are imported from India • Limited capacity for imported medicine inspections makes it hard for higher standard local products to compete	**Increase inspection controls** • Reduce the importing of low standard compliance products by increasing testing and related capacity • Tighten the requirements for the imports of the categories which are locally produced, only allowing imports of high quality standards	• Pharmacy and Poisons Board	"PPB has **limited capacity to enforce GMP compliance** consistently and continuously"

Source: Interviews with Manufacturers, IFC Kenya Pharmaceutical Industry Diagnostic Report 2020

2. 2-3 additional factories would have to be installed to substitute imports of new products creating 600-900 jobs

Manufacture new final dosage form products for KEMSA and the private market

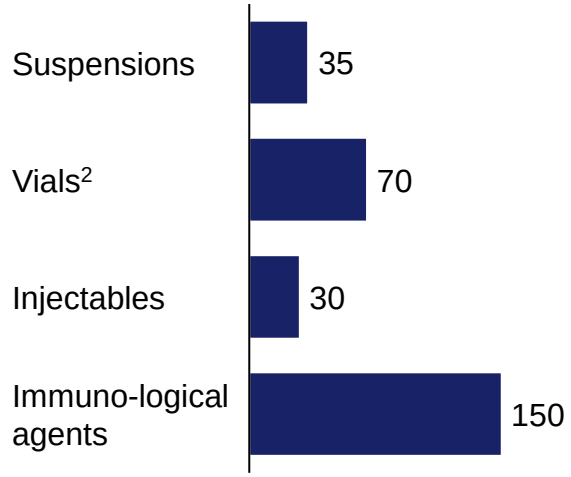
PRELIMINARY DRAFT

Background of the opportunity

Imports of products that are not locally manufactured

~40% of the Supplies to the RDF and ~70% of private market are imported – these include products which could be manufactured locally through focused efforts

Strictly Imported drugs, $m



X68%

Procured by KEMSA & Private sector

$ 150-200 m

Opportunity size[3]

Potential facilities and impact[1]

2-3

new facilities
Could be developed to support the import substitution of newly manufactured products

600-900

jobs created

1. Assumptions: Single facility generates $60m revenue and creates 300 jobs
2. Including insulins
3. These impact estimates would need to overlayed with current interest among local manufacturers or potential new entrants

Source: Interviews with Manufacturers, IFC Kenya Pharmaceutical Industry Diagnostic Report 2020

2. There are three main barriers that may need to be unlocked to enable manufacture of new products

Manufacture new final dosage form products for KEMSA and the private market

PRELIMINARY DRAFT

Main Barriers	Potential unlocks	Stakeholders involved	What we heard
• **Insufficient available market information** for manufacturers to plan which new medicines they can manufacture	**Publish publicly accurate consumption / procurement data** • Increase market transparency through public market reports, transparent tender processes, records, etc.	• KEMSA • PPB	"**KEMSA data needs to be open and transparent**"
• **Long approval times for drug registrations** that take over 1 year and slow down the ability to compete with newly off-patented molecules – takes longer to scale the industry and compete with imports	**Improve speed of drug registration processes** • Enable quicker registration of local manufactured drugs to get preliminary approval within weeks and final approval shortly after • Improve registration training and capabilities	• PPB	"Drug registration process needs to be simplified – **India can certify a new drug in 2 weeks**"
• **Low guaranteed demand** preventing the investment into new products as entities do not know if they will recoup	**Offtake agreements with local manufacturers** • Provide binding agreements that commit a share of procurement to local manufacturers starting to produce specific products for up to 3 years • Provide favourable volume / contract term policies for local manufacturers	• KEMSA • Donors to help with financing the investment	"There is no commitment to long term demand **– investing in new product capacity can be a gamble**"
• **Lack of equipment, capabilities /** talent and scientific processes needed to manage scaled complex product manufacturing	**Partner mentoring program** • Actively promote capabilities and skills from high standard partners to manufacture more complex products	• MNCs • UNIDO • Intl. Universities • Manufacturing hubs for exchanges (e.g. India, SA)	"Harder to get the **quality of these imported products up to GMP standards**"

Source: Interviews with Manufacturers, IFC Kenya Pharmaceutical Industry Diagnostic Report 2020

3. 4-5 new facilities would allow to Kenya to serve the regional market creating 1,200-1,500 jobs

Expand capacity of existing products for regional export

PRELIMINARY DRAFT

Background of the opportunity

Kenya currently represents only 5% of the pharmaceutical exports in the region

- Potential strong pharma exporter who can aim to increase this market share
- Main opportunities are Tanzania, Ethiopia, Uganda, Rwanda, Burundi, South Sudan

Kenya currently manufactures 30% of their own market – this can be scaled to provide these supplies to the under penetrated region

Key assumptions:

- Rest of E. Africa is worth $2.1bn and distributor margin is ~20%
- Export targets have the same market dynamics as Kenya (e.g., the need for the same medicines = 30%)
- There are no restrictions on these medicines by export target countries
- There is no limit to demand or funding for these products

$250 – 300M

Opportunity size[2]

Potential facilities and impact[1]

4-5

new facilities could be developed to scale exports of locally manufactured products to the region

1,200 – 1,500

jobs created

1. Assumptions: Single facility generates $60m revenue and creates 300 jobs
2. These impact estimates would need to overlayed with current interest among local manufacturers or potential new entrants

Source: Interviews with Manufacturers, IFC Kenya Pharmaceutical Industry Diagnostic Report 2020

3. There are three main barriers being to increase regional exports requiring several stakeholders to come together

Expand capacity of existing products for regional export

PRELIMINARY DRAFT

Main Barriers	Potential unlocks	Stakeholders involved	What we heard
Regional harmonization across region as each country has their own • Unique verification process and fee • Protectionist policies (e.g., preferred medicines list and pricing)	**Accelerate the harmonization process** • Recognise origin certifications across the region and with a single minimum compliance standard • Improve customs clearance processes to reduce time to market • Reduce Common External Tariff	• National Governments • Regulatory authorities • Ministries of health • Customs authorities	"Local authorities are less strict on their own manufacturers – **there should be one standard**"
Stabilise incentives • Policies to drive investment have been altered within a few years of being implemented creating uncertainty for forecast planning and scaling through investment	**Strengthen regional supply chain networks** • Improve Border clearance processes to reduce time to market • Increase rail and road opportunities	• MoITED • National Treasury • Ministry of Health	"We invested in new capacity and the **change in tax incentives hurt our cashflow planning**"
Pricing competitiveness to export Kenya will be competing with other exporting countries (e.g., India) and incurring additional costs • No pricing concessions • Import tariffs added • Verification process costs	**Regional pricing instruments** • Pricing instrument (e.g., tax, subsidy, regional preference) to support local producer positions in the region • Regional focused tender processes	• Local manufacturers • National procurement authorities (e.g., KEMSA, EPSA)	"There are **too many non-tariff barriers** (e.g., VAT, IDF & RDL[1]) that increase cost manufacture for these markets"

1. Import Declaration Fee and Railway Development Levy (both increased in 2019)

Source: Interviews with Manufacturers, IFC Kenya Pharmaceutical Industry Diagnostic Report 2020, Press Scan

4. Improving standards to export existing products will strengthen Kenya's local manufacturing

Improve standards for export of existing products to SRA countries

PRELIMINARY DRAFT

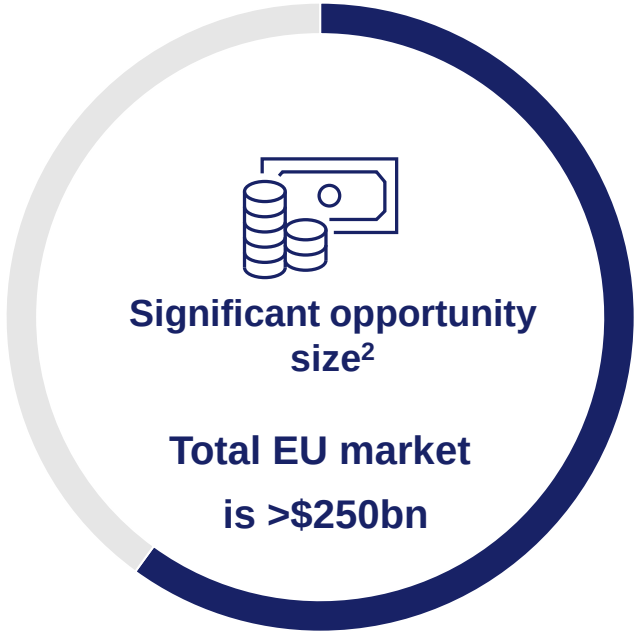
Background of the opportunity

Exports to SRA countries are only ~$3.5 m, representing **<3% of Kenya exports**

Exporting to SRA countries creates an opportunity to increase the standards of the Kenyan local production and increase addressable markets

This with further

- Develop new skills
- Encourage new investment
- Improve supply chain security



Potential facilities and impact[1]

New facilities would need to be developed to scale exports of locally manufactured products to Europe

This could create a significant number of jobs

1. Assumptions: Single facility generates $60m revenue and creates 300 jobs
2. These impact estimates would need to overlayed with current interest among local manufacturers or potential new entrants

Source: Interviews with Manufacturers, IFC Kenya Pharmaceutical Industry Diagnostic Report 2020

4. To export simple products to SRA countries, national manufacturing standards would need to be improved

Improve standards for export of existing products to SRA countries

PRELIMINARY DRAFT

Main Barriers	Potential unlocks	Stakeholders involved
• **Limited inspection availability** for international standard compliance	**Supporting capability building programs** • Sponsoring training and internship programs for the country nationals to cater for pharma investors talent needs in quality control for exports • Work with SRAs (e.g., EMA, FDA) and WHO regulatory teams to strengthen national regulatory capabilities to meet more stringent requirements	• Pharmacy and Poisons Board • SRA and WHO • Intl. Certification Agents
• **Limited local capabilities** to produce at SRA standards	**Invest in stringent manufacturing capabilities at select high potential sites** • Strengthen skills (e.g. training programs in collaboration with MNCs) • Strengthen plants (e.g. upgrade production lines meet SRA compliance standards)	• Local manufacturers • MoITED • Development finance institutes

What we heard

"We need to produce at a higher GMP standard than locally available – this will **require additional inspections from international regulators**"

"**Significant investment is needed to improve local capabilities**"

Source: Interviews with Manufacturers, IFC Kenya Pharmaceutical Industry Diagnostic Report 2020

5. 10-15 new facilities could be developed to allow Kenya manufacturers supply APIs to the region

Manufacture API's for local and regional market

PRELIMINARY DRAFT

Background of the opportunity

Production of APIs will **enable Kenya to move down the value chain** into more advanced industries

Analgesics and systemic antibacterials are among the most consumed simple products – making APIs for these products is expected to be the most feasible

- API plants are subject to the cGMP regulations and relevant country regulatory approvals
- API plants can be multiproduct purposed (e.g. run 2-4 months of production for one product and then switch)

Key assumptions:

- Total EA market is ~$3.4bn and distributor margin is ~20%
- Only analgesics (~3%) and systemic antibacterials (~16%) will be self sufficient enough for APIs
- APIs are assumed ~35-40% of the cost of material

Potential facilities and impact[1]

10-15
new facilities

Could be developed to support the manufacturing of APIs for the region

1 000 – 1 500
jobs created

1. Assumptions: Single facility generates $20m revenue and creates 100 jobs
2. These impact estimates would need to overlayed with current interest among local manufacturers or potential new entrants

Source: Interviews with Manufacturers, IFC Kenya Pharmaceutical Industry Diagnostic Report 2020

5. A consortium would be needed to manufacture API's for local and regional market

Manufacture API's for local and regional market

PRELIMINARY DRAFT

Main Barriers	Potential unlocks	Stakeholders involved
• **Lack of industry maturity** creating capabilities shortfalls as well as scale required to sustain the demand for APIs	**Public private partnership (PPP) for API production** • Establish a consortium for API production possibly led by the government in which competitors would co-invest, in order to make it feasible to produce API's locally **Support talent building** • Develop supportive environment for talent importing of specialized pharma skills (e.g. fast tracked visas) to train local persons • Requires skilled chemistry and process engineering skills	• MoITED • Department of Home Affairs • Local manufacturers
• **Limited scale** to compete with India and China	**Develop national support plan** • Develop national plan to support API production domestically (e.g. preferential pricing for domestic APIs, secured government offtake, upfront investment in backward value chain)	• MoITED • National Treasury • KEMSA • PPB

What we heard

"APIs cannot be manufactured today – **we first need to be self sufficient in many medicines** before we can backward integrate the value chain"

"We **currently have no available talent for API manufacture**"

"APIs manufacturing will **require committed Government support** and a focused aspirational action plan if it is to succeed"

Source: Interviews with Manufacturers, IFC Kenya Pharmaceutical Industry Diagnostic Report 2020

5: API manufacturing is currently unlikely due to the cost, competition from India and China, and required level of scale and expertise

Consideration for API manufacturing

Market		Diseases such as malaria, HIV/AIDS and TB have an outsized burden in Africa and will have sufficient demand
Complexity	**Molecule size**	Small molecules (e.g., paracetamol) are easier to produce
	Process	Processes such as fermentation or additional purification will require additional investment
Commercial viability	**Investment required**	Capex required will range from $20 – 50mn based on current facilities and capabilities
	Competitive landscape	India and China can produce APIs at scale making them cost competitive

However, local API manufacturing is unlikely in the near term due to three key reasons

Investment required	Setting up an API production plant is **costly** (up to $50 Mn) and dependent on factors such as **infrastructure, raw material availability, sophistication**. It can also take 5+ years[1] to set up the infrastructure and ecosystem required
Competition from India and China	API production is a **low margin business** which requires scale that Kenya lacks. In addition, countries such as **India are incentivizing manufacturers to produce APIs** which makes it a more attractive market for foreign investors
Technical expertise required	API production requires **specialised skill in chemicals and engineering processes** which is limited in Kenya given the scale of the chemicals industry

1. Timeline provided by the Indian government to support the setting up of a pharma park

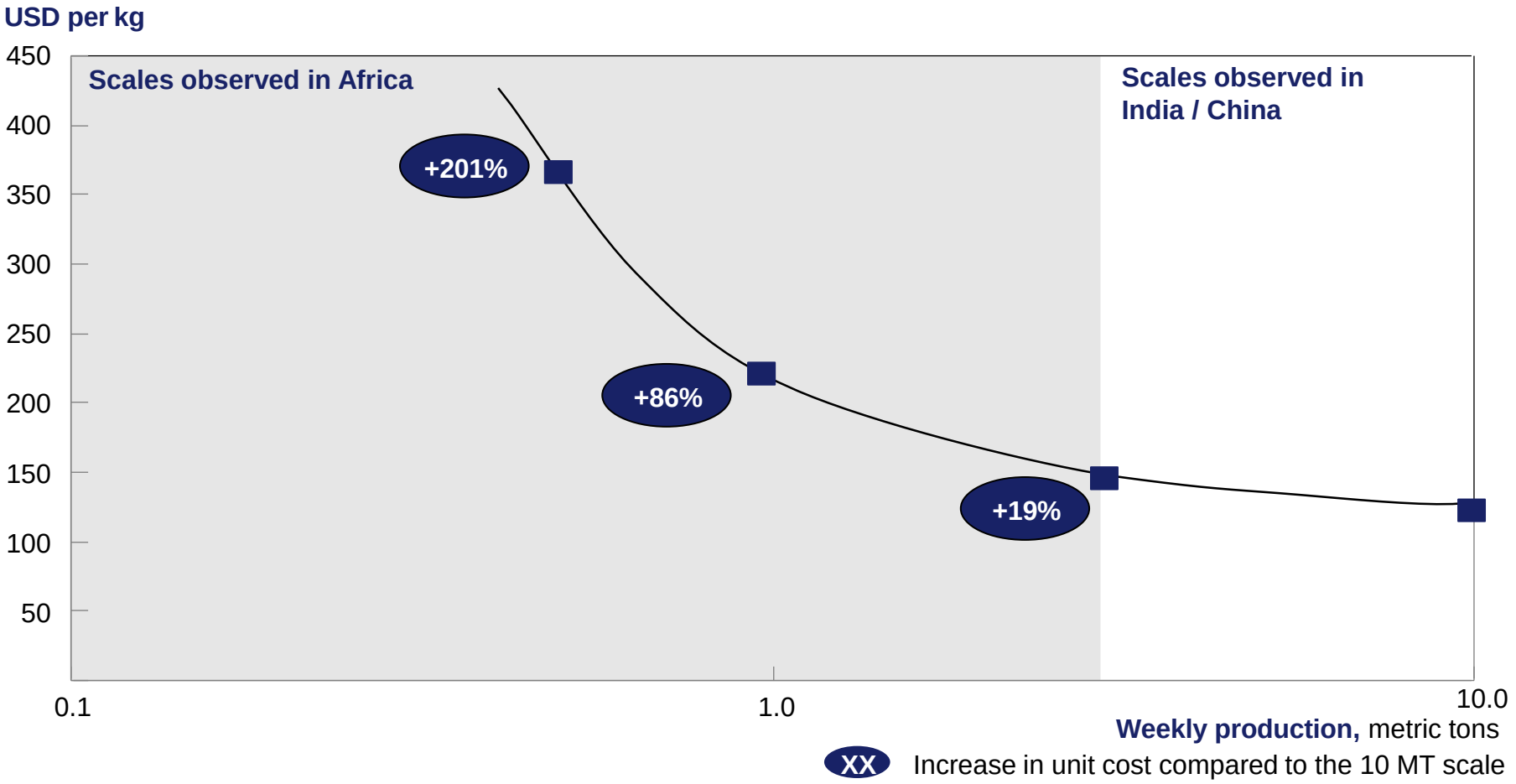
Source: Expert interviews

African manufacturers struggle to attain economies of scale compared to Chinese and Indian competitors

API manufacturing is very competitive and fragmented market

ILLUSTRATIVE

Estimated unit cost of one kg of API nevirapine based on the scale of the production unit[1]

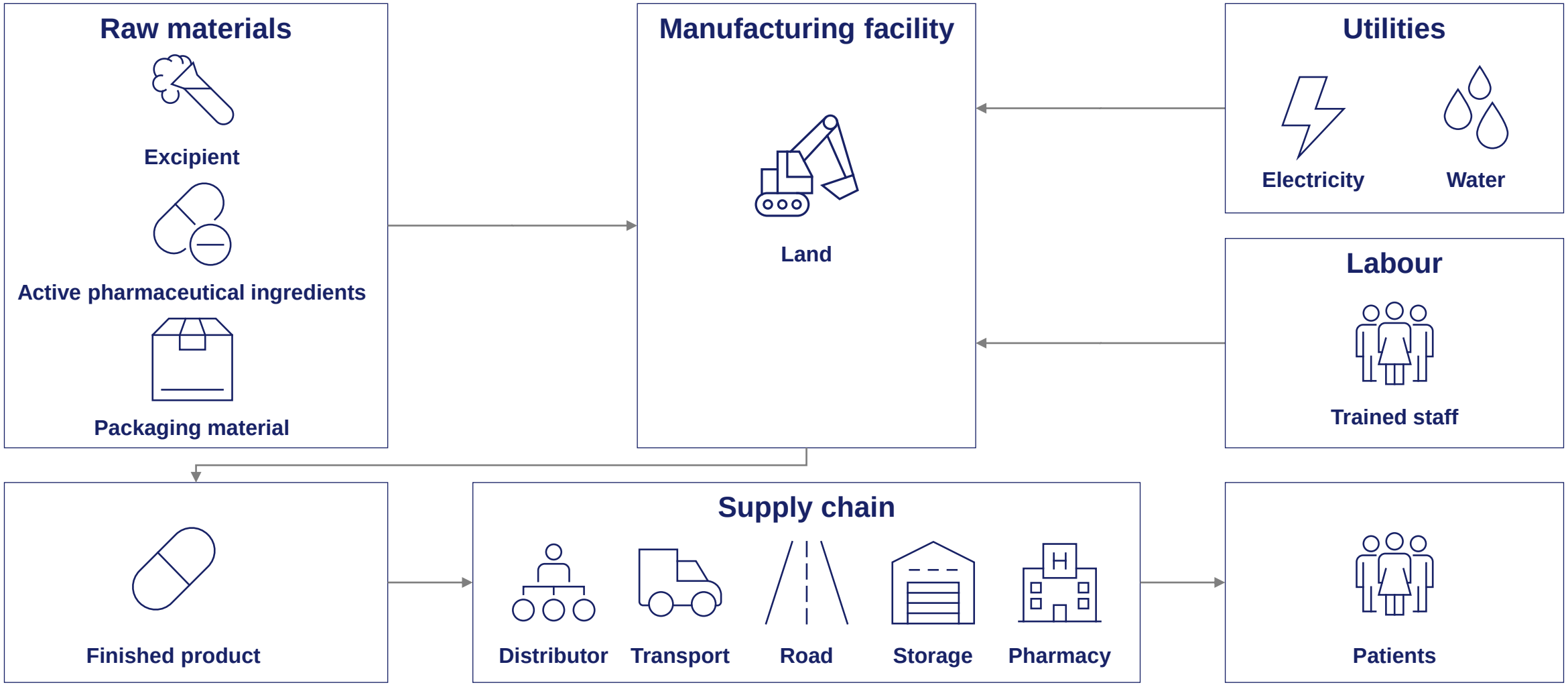


Production costs multiplied by 2 or 3 on average for a ton of API produced in Africa vs China or India

1. Production M4All en lot

Source: National and international expert interviews

Key requirements for pharmaceutical manufacturing



Source: IFC Kenya Pharmaceutical Industry Diagnostic Report 2020

Summary of challenges affecting industry stakeholders

Regulatory

- Regulations supporting import-driven market
- Inability to strictly enforce GMP guidelines
- Presence of unregistered pharmacies
- Manufacturers' lack of documentation skills delays the registration process
- A lack of PPB inspectors to manufacturing jobs inspect local and foreign manufacturers affects GMP enforcement

Operational

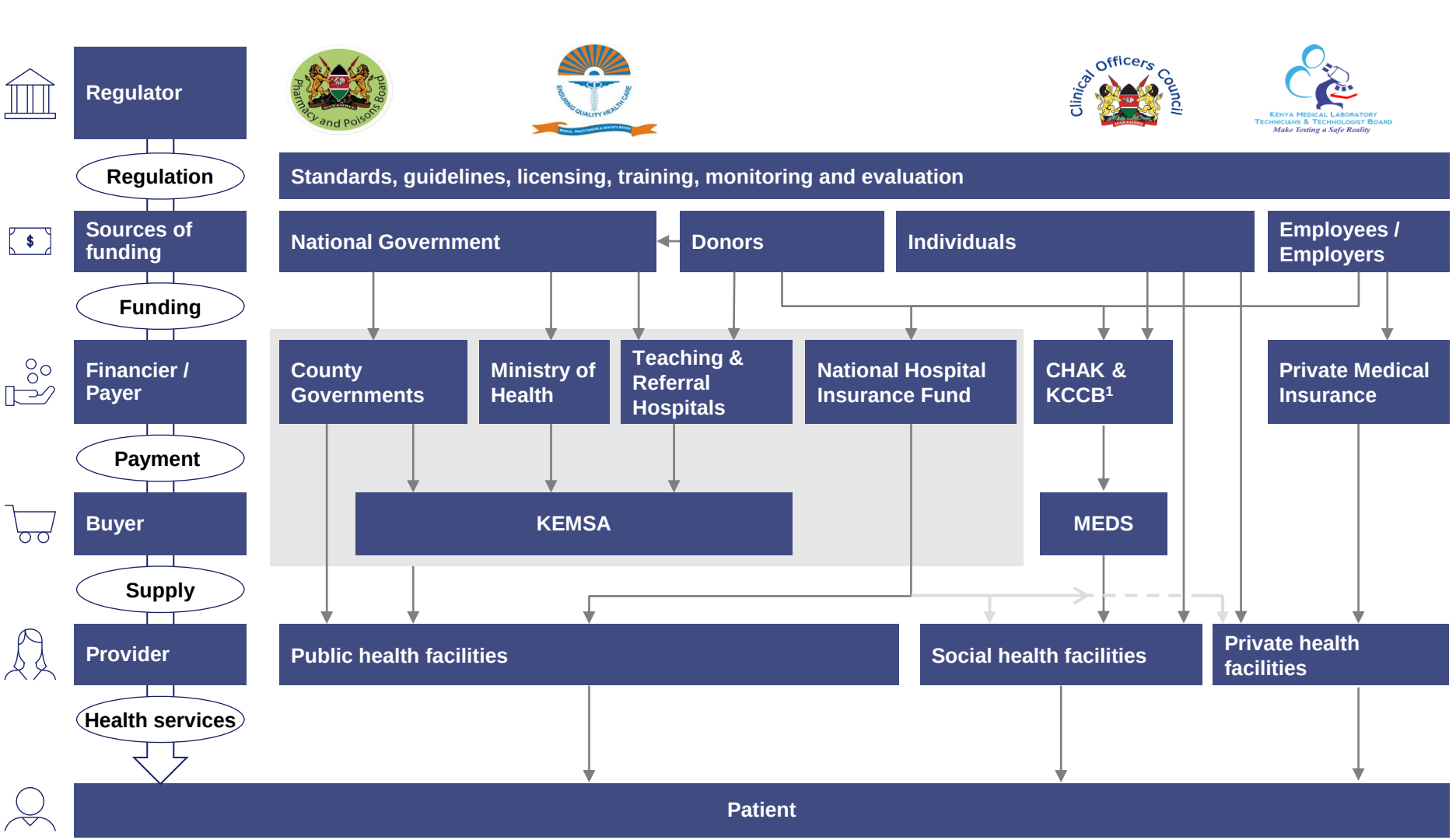
- Raw materials are not locally manufactured and readily available
- Equipment and spare parts are not locally available
- Access to land is a problem
- Electricity supply is costly and of poor quality
- Water supply is inadequate
- Workforce is inadequately trained and cost of labor is high
- Multiple inefficiencies in supply chain
- High cost of capital

HR Challenges

- Skill gap among workforce (especially industrial pharmacy)
- Curriculum too theoretical
- Lack of collaboration between industry, academia, and regulator
- Scarcity of other skills such as engineering and business
- Students lack interest due to scarcity of manufacturing jobs

Source: IFC Kenya Pharmaceutical Industry Diagnostic Report 2020

There are 5 main public funding stakeholders in the health space…



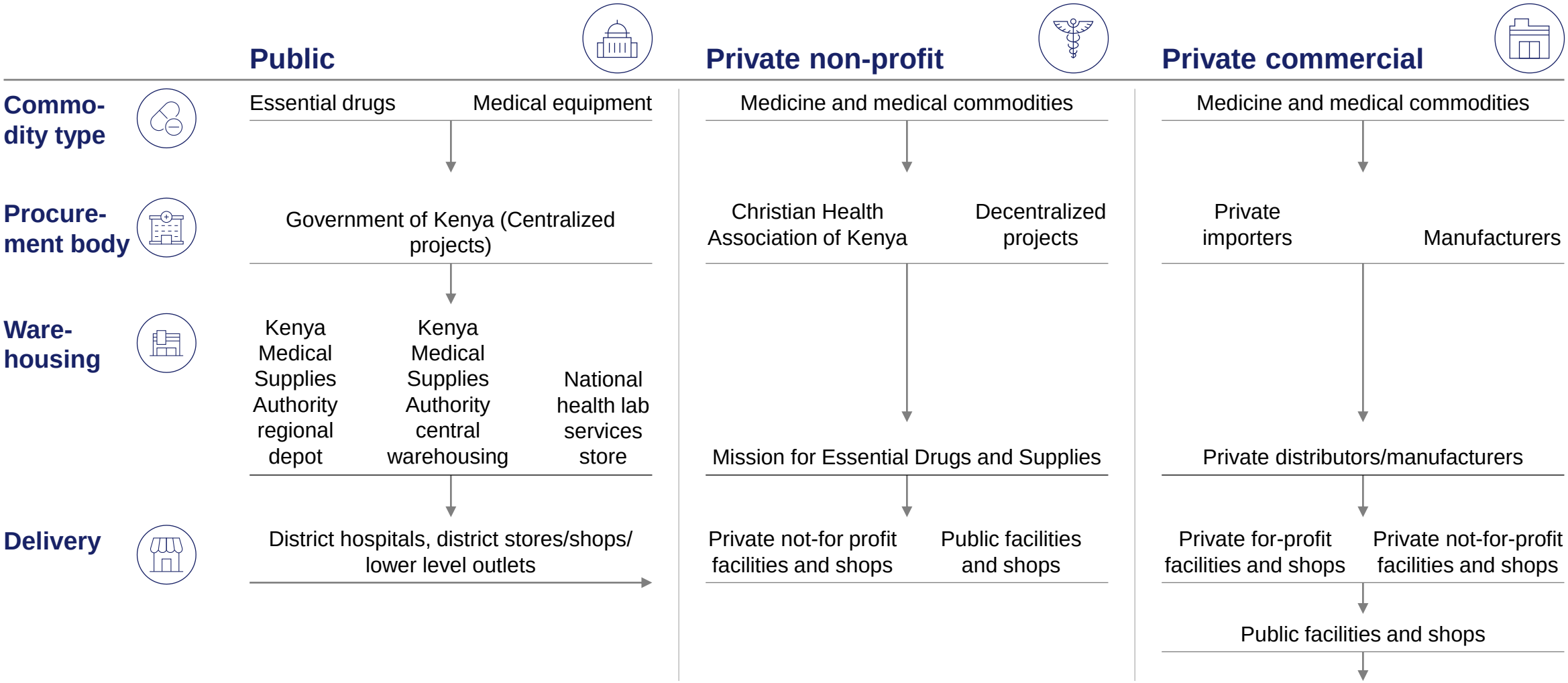
Key insight

- Public health financing is complicated and fragmented as there are several stakeholders with differing aims
- There are 4 sources of funding
- Donors and individuals focusing on preventative care (i.e. Vaccines & WASH programs), family planning, Malaria, TB and HIV

1. Christian Health Association of Kenya (CHAK) and Kenya Conference of Catholic Bishops (KCCB)

Source: Team analysis; Expert interviews

… Each with different pharmaceutical supply chains



Source: IFC Kenya Pharmaceutical Industry Diagnostic Report 2020

The development of a national incentive program is key to develop the pharmaceutical industry

Example initiatives from select countries

Value Proposition	Initiative	Solution	Countries
 **Pharma-sector ease of doing business**	Fast track registration of drugs	It is an initiative that aims to accelerate the entry of local manufacturers products to market. This will enable rapid commercialization and revenue generation	UAE Russia
	Key account managers support to investors	Assigning key account managers to help investors setup their business and navigate the local ecosystem	Turkey Ethiopia
	Accounts receivable financing	An enforcement tool to provide more certainty of payments to investors and help them avoid potential cashflow issues	USA
 **Market access**	Offtake agreements	De-risk market entry by providing a binding agreement that commits a specific share of procurement to a specific local manufacturer	Brazil Russia
	Price preference for localization	A price preference mechanism based on the degree of localization a pharm investor	Brazil
	Publication of pharma investment activity	A comprehensive and granular set of reports published semi-annually covering the ongoing and expected pharma projects in the country	USA
	Export support services	Attracting investment through creating an effective export hub. This will allow investors to manufacture locally and generate revenues from accessing other markets	India
	Dual pricing at Food and Drug Regulator to enable exports	An improved reference price system based on registration of two price points that will allow investors to sell their products at a higher price in export markets	Croatia
	Boosting exports through foreign aid agencies	A volume commitment by the Government for vaccines exports as part of the country's foreign aid	China
 **Financial Incentives**	Industrial Development Fund loans	Government loans to pharma investors with special eligible amounts and payment terms to reduce the financing cost	Ireland India
	Strategic investment in new drug discovery	Providing investments through the Intellectual Property Fund for new drug discovery	France
 **Talent**	Flexible local talent development requirements	An investor-friendly set of local talent development exceptions to enable the quick ramp up of needed skilled resources	Ethiopia Oman
	Supporting capability building programs	Sponsoring training and internship programs for the country nationals to cater for pharma investors talent needs	Australia Ireland

Source: Press scan, Expert interviews, McKinsey PMP Practice, case studies