Potential in local pharmaceutical manufacturing in Ethiopia

Consolidated study report

December 2023

The contents of this document are meant to be informative of a fact base, rather than provide any specific recommendation. They are based on initial research, interviews, and analysis and are subject to change given continued feedback

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MINISTRY OF HEALTH - ETHIOPIA

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Ethiopia can build on relevant strengths to be a competitive hub of pharmaceutical manufacturing

Strong government support	• The **Ethiopian Government has prioritized the pharmaceutical manufacturing sector** • Through its 10-year national strategy for pharma manufacturing, Ethiopia has set a goal to become a **pharmaceutical manufacturing hub** by 2025. **Commitment has been reinforced recently** by the recent of FX access to local manufacturers to buy raw materials
High connectiveness	• Ethiopia is well connected to the rest of the world by air transport, **with ~80 country connections, more than any other African nation** (as of November 2023). • Relevant because **air logistics is a key mode of transport** for finished pharma products
Access to local and export market	• Ethiopia has the second-largest population in Africa with 120M inhabitants, and a **local pharmaceutical and medical device market of $1.3 – 1.7 Bn in 2022,** and in the long-term could become even more significant if per capita consumption matches other big African economies • Has the potential to serve as an **export hub** for the > $30 Bn pharmaceutical market in Africa
Extra capacity and ready to be used infrastructure	• Kilinto park is Africa's first **dedicated industrial park to pharmaceutical manufacturing** and is state-of-the-art, covering 270 hectares of land and being **equipped with all necessary infrastructure** including wastewater treatment plants • Local manufacturers are **operating at only <25% capacity**
Abundant and low-cost labor force	• **Productive labor force** with more than 60% of Ethiopia's population between the ages of 15-65 • Cheap labor force, with **potentially up to 30% more cost-productive labour costs** compared to India

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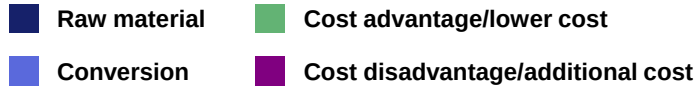
Ethiopia could have potential conversion cost advantages in tablet & capsule manufacturing

Assumed at large scale for best-in-class manufacturers producing high value API drugs



Cost categories[1]	Subcategories	Subcategory shares, % of categories	Local cost competitiveness	Ethiopia's relative competitive local disadvantages against best in class	Average additional cost
Raw material[2]	API[4]	60-70%	15%	Local cost disadvantages may be present due to small scale & lack of upstream integration	10-15%
	Excipient	15-25%	10%	Cost disadvantages may be present due to small scale & lack of upstream integration	
	Packaging	10-20%	10%	Cost disadvantages may be present due to small scale & lack of upstream integration	
Conversion	Utility	10-20%	-30%	Utility costs are much lower vs. India or China. However, there is less stability of supply	(-15)–(-10)%
	Labor	35-45%	-30%	Labor costs are substantially lower locally but to some extent, offset by low productivity	
	Machinery	20-30%	10%	Costs are higher due to logistics & less developed ecosystem, which can be higher due to lack of economies of scale	
	Other costs[3]	20-30%	0%	Might be lower for scale local producers, but is estimated to be equal at realistic scale	

1. This cost structure is excluding margin 2. Raw material cost is only looking at the FOB cost and the share may change per drug 3. Most other costs are related to conversion costs such as consumables, spare parts, quality and compliance 4. This is for high-cost API drugs. However, API costs and share of the of the manufacturing cost can significantly change can be 50% lower in share of manufacturing cost for low-cost API drugs

Source: Expert interviews

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Local manufacturing of drugs for local demand could become competitive in the medium to long-term

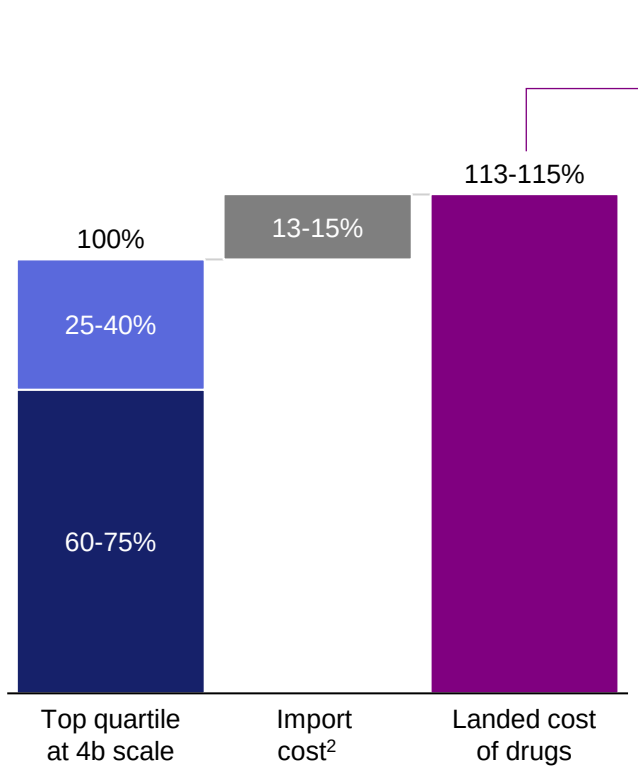
Conversion
Raw material
Import and duties cost
Landed cost of drugs

XX Additional cost to on local manufacturers relative to best-in-class

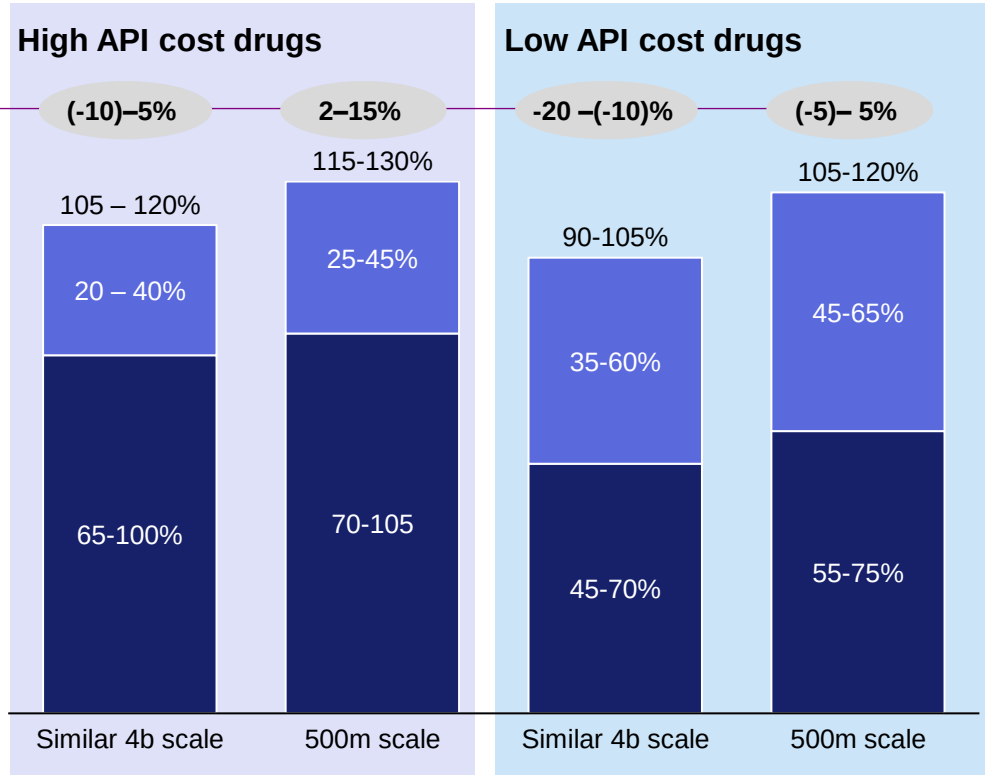
Main pre-conditions

- Local manufacturers **produce at top quartile operational efficiency,** which is difficult to achieve and takes significant amount of time (at least 3-4yrs.)
- Manufacturers achieve **large scale production** volumes, **by obtaining access to international markets** through the adoption of more export friendly FX rules and other market access initiatives
- **Local production conditions such as; utility stability and labor productivity** are high and are competitive with best-in-class producers

Cost of importing drugs from top quartile, % of cost per tablet



Relative cost of production in Ethiopia[1], % of cost per tablet



Local manufacturers in median performance, can have additional 5-15 p.p. cost of manufacturing, which makes them less competitive (esp. at lower scales)

1. Relative cost of production of local manufacturer producing programme, compared to best-in-class manufacturer
2. Import cost is airfreight, transport insurance and any other logistics related costs. There are also some duties that apply such as contribution tax accounting up to 5%. This is based on an average for imported products from best-in-class (India)

Source: Expert interviews, McKinsey benchmarking tool (POBOS), Prices and availability of locally produced and imported medicines in Ethiopia (WHO)

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In the long-term if raw material sourcing is further improved, Ethiopia could become a high potential exporter

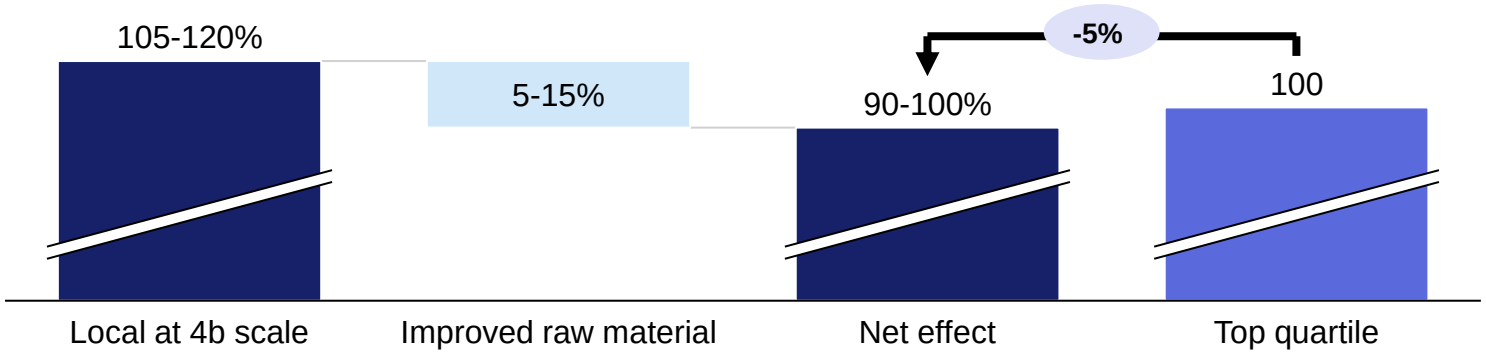
Top quartile performance achieved for local manufacturers at scale

xx Average relative cost difference

- Local manufacturers have additional costs relative to best-in-class **due to the logistics cost of importation of raw materials and lack of vertical integration**
- **Raw material disadvantages significantly affect drugs that have a high cost of API**, which are typically program drugs like TLD and TLE
- **If local manufacturers can procure raw materials locally, they can significantly be competitive** with best-in-class players
- They can also explore the potential for local manufacturing of raw materials in the long term

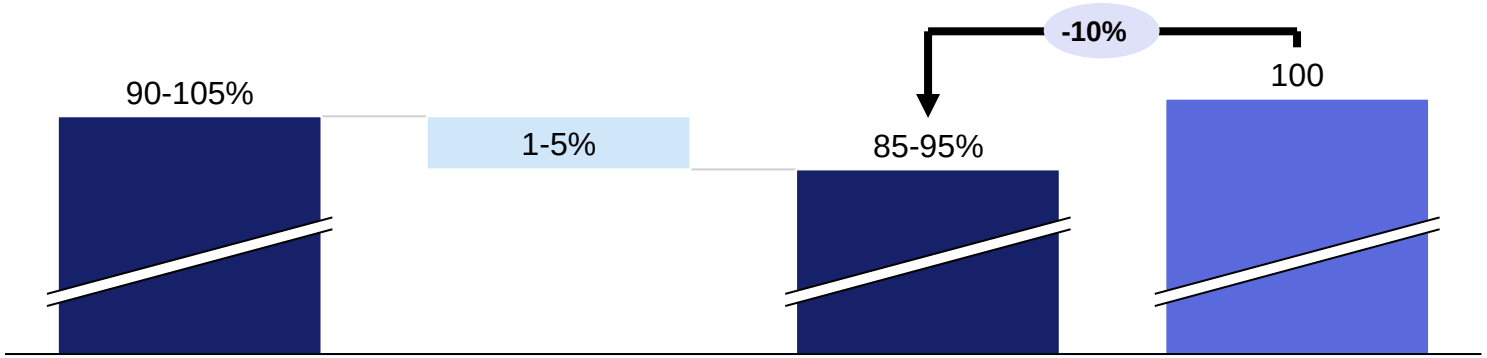
High API value drugs cost comparison relative to best in class,

% of cost per tablet



Low API value drugs cost comparison relative to best in class,

% of cost per tablet



Local manufacturers in median performance, can have additional 5-15 p.p. cost of manufacturing, which makes them less competitive (esp. at lower scales)

Source: Expert interviews, www.naruc.org, https://www.globalpetrolprices.com/India/electricity_prices/

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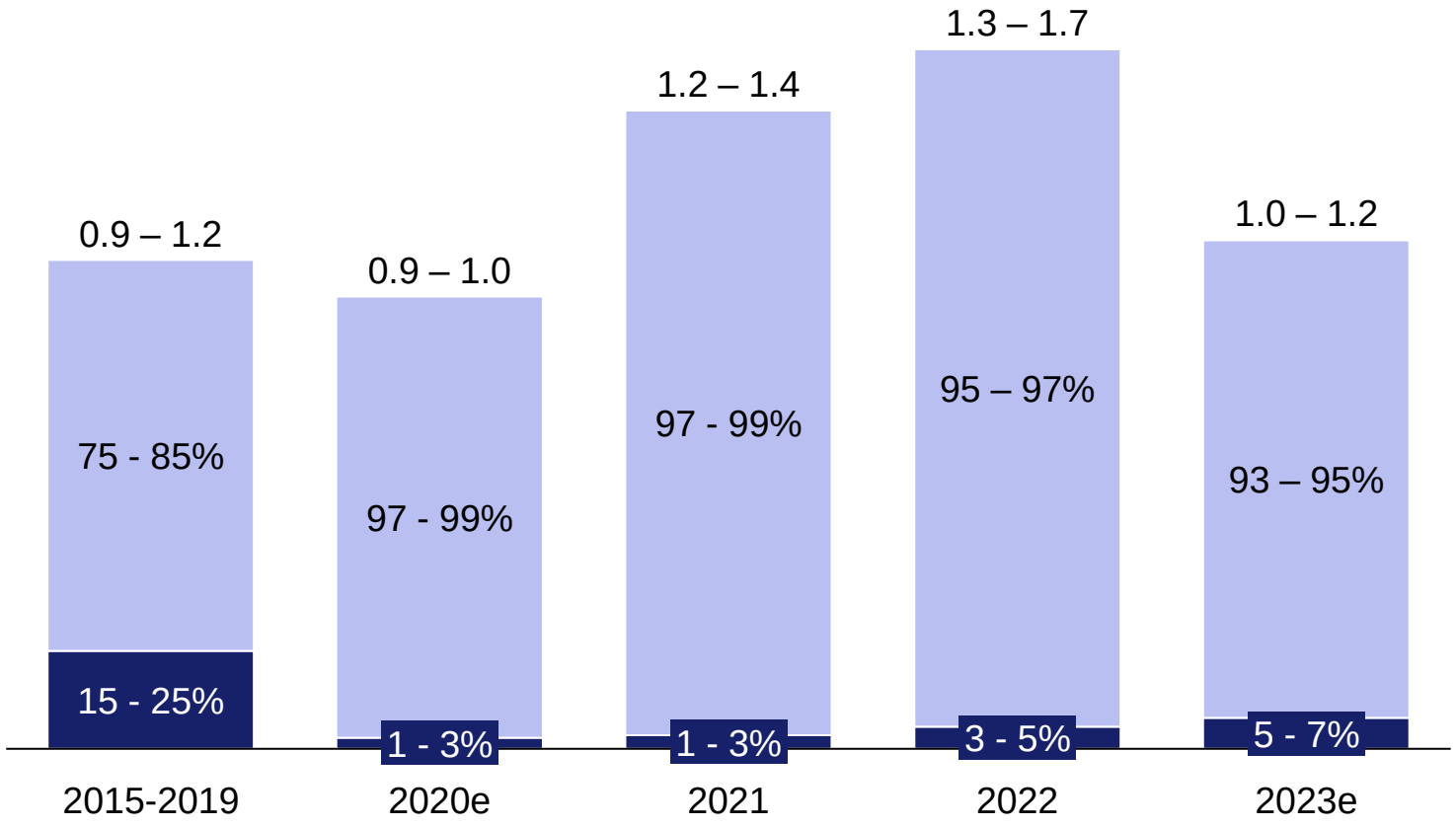
Despite its' potential, the local pharma manufacturing industry has been losing relevance, ~4% of the total purchased products were locally manufactured in 2022

Pharmaceutical and medical devices sales (USD billion), historical data



NOTE: For the purpose of this analysis, private sector data was estimated. E=Estimated full year data.
Source: EPSS Procurement data (2020-2023), EIC Pharma Strategy report (2020), Fitch Solutions (2023)

Key considerations

- Ethiopia **produced a quarter of its pharma products locally** from **2015 to 2019** but experienced a substantial drop to only **3-5% in 2022**
- Economic challenges, including **access to forex,** and challenges related to the **recent conflicts**, have likely contributed to the decline in local pharmaceutical manufacturing

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Scale is an important determinant of pharmaceutical production efficiency

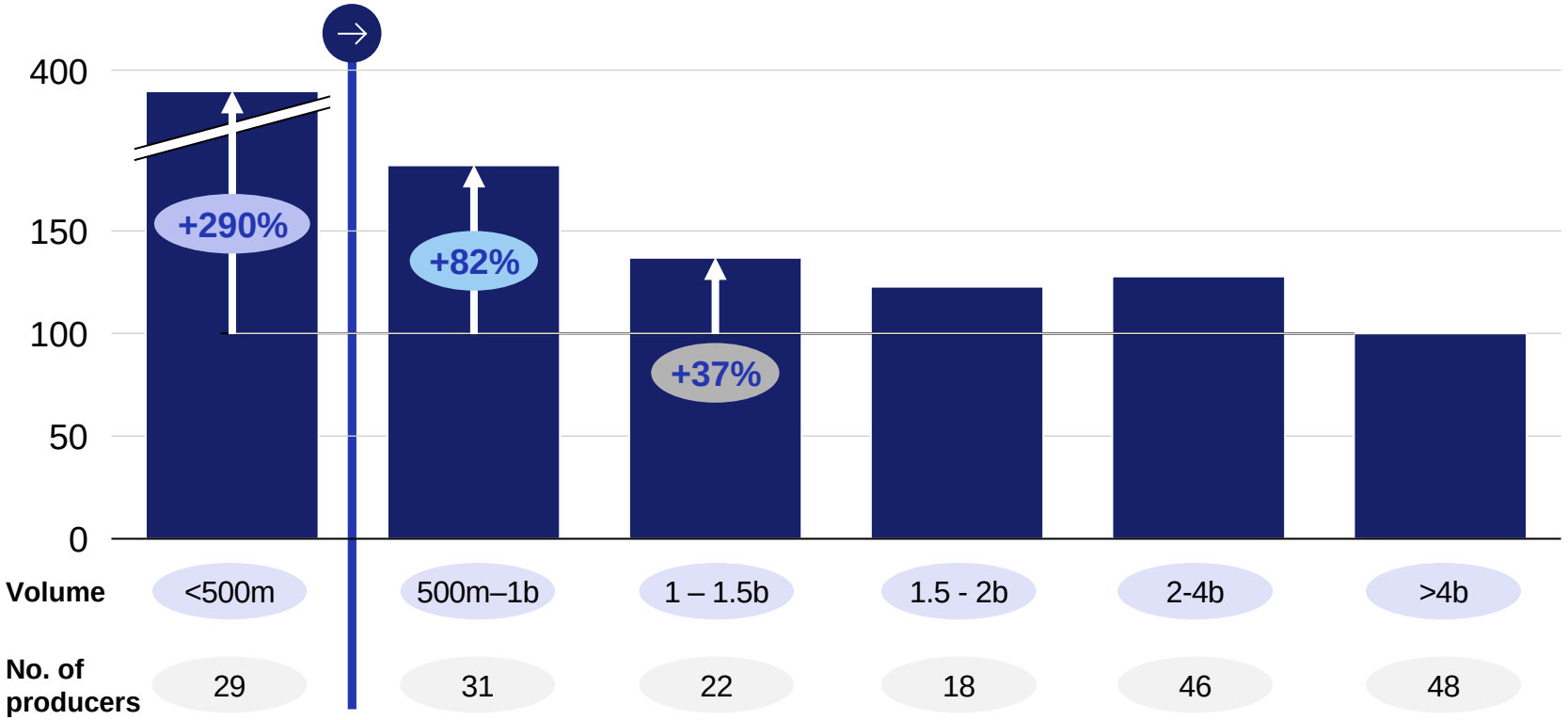
xx Top quartile comparison for 500m vs >4b

xx Top quartile comparison for 500m – 1b vs >4b

xx Top quartile comparison for 1 – 1.5b vs >4b

Optimal volume for competitiveness

Normalized conversion cost of top quartile performers PU[1,2], Top quartile cost at scale of >4b = 100



Key insights

- It is **difficult to be competitive at scales below 500m per year**, due to relatively very high conversion costs
- **Scale is important to keep conversion costs low**
- However, there is a **significant variance in conversion costs among manufacturers** producing at the same scale

1. Based on McKinsey global pharmaceutical benchmark of ~200 pharmaceutical manufacturers around the world
2. Normalized median cost per unit (PU) is normalized against the top performers which scale of above 4b = 100. All the other medians and quartiles are relative to top performers

Source: McKinsey benchmarking tool (POBOS)

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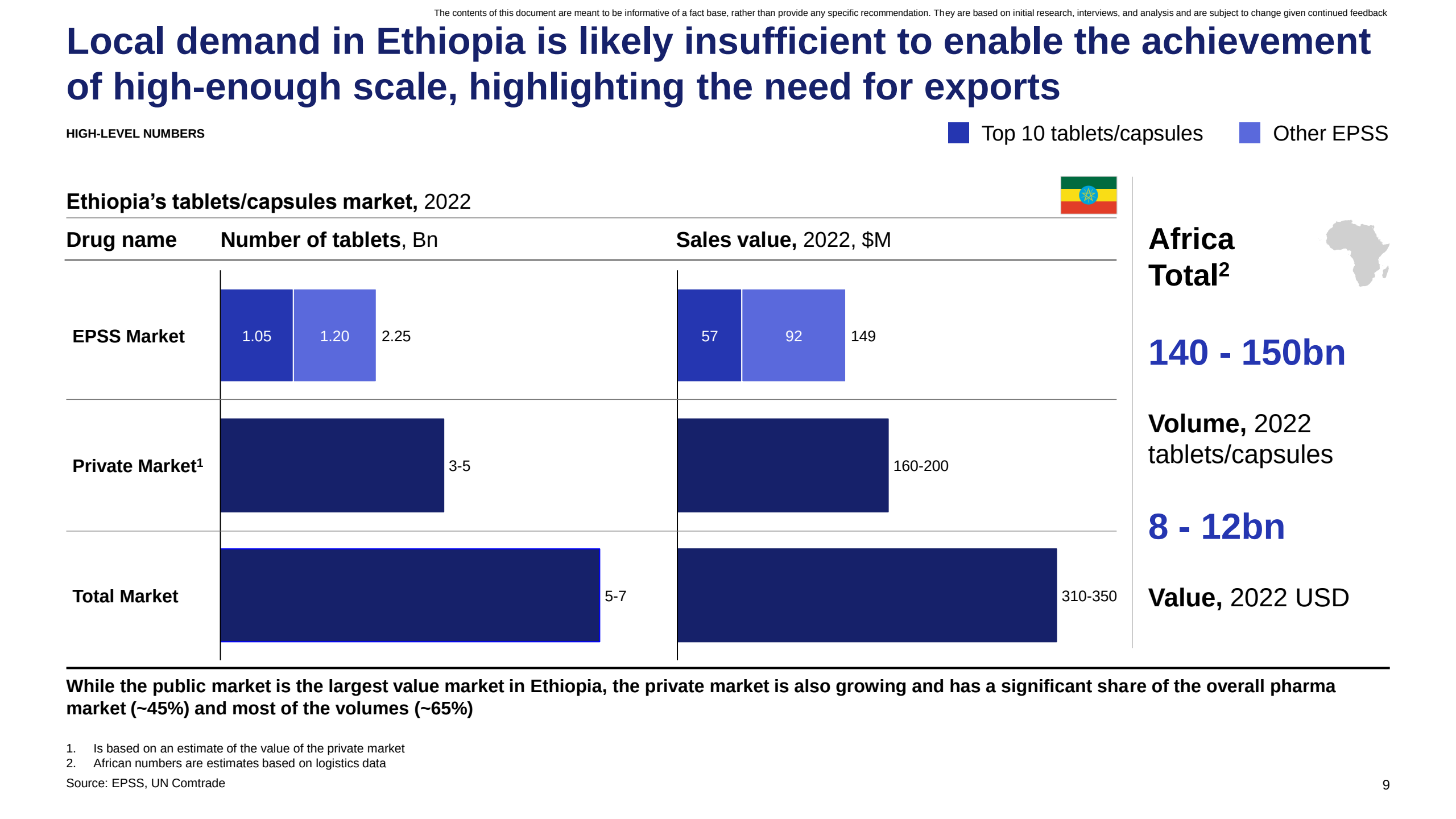
Local demand in Ethiopia is likely insufficient to enable the achievement of high-enough scale, highlighting the need for exports

HIGH-LEVEL NUMBERS



While the public market is the largest value market in Ethiopia, the private market is also growing and has a significant share of the overall pharma market (~45%) and most of the volumes (~65%)

1. Is based on an estimate of the value of the private market
2. African numbers are estimates based on logistics data

Source: EPSS, UN Comtrade

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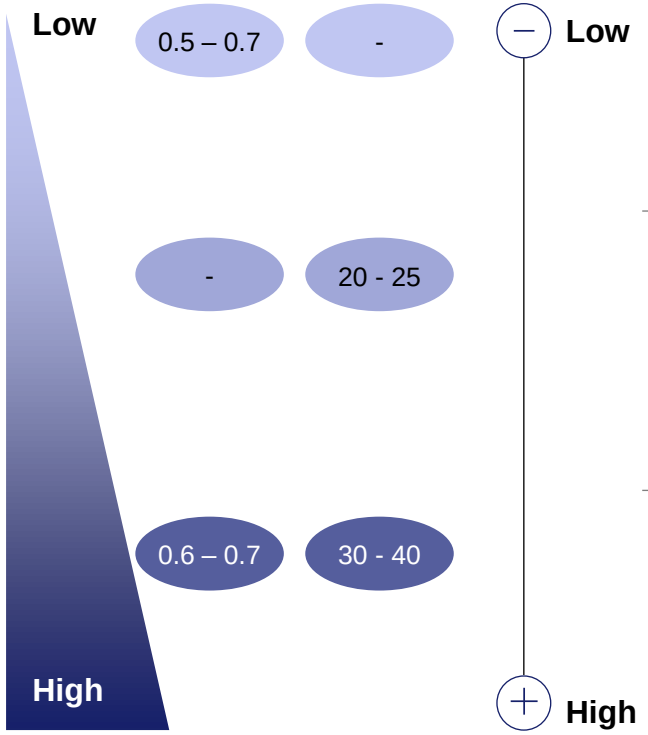
However, to be able to access the large export markets and donor markets, high regulatory requirements must be met

$B, 2022



Regulatory requirement	Focus market	Description
Low	1 **Local non-donor market**	Manufacturing companies focus on serving the **local non-donor Ethiopian market,** i.e., the public and private sector
	2 **Africa non-donor market**	Manufacturing companies focus on **non-donor export markets** to **countries with low regulatory requirements**, i.e. National regulatory authority (NRA) in Africa
High	3 **Global donor market**	Manufacturing companies focus on serving **donor-funded markets** both locally and globally

NOTE: 1. Ethiopian pharma market size in 2022 is worth ~$1.5Bn, of which 45% is estimated to be donor funded. 2. African pharma market is worth ~$35Bn in 2022, of which 30-40% is estimated to be donor funded. 3. Donor market size was extrapolated using the global ~57Bn of development assistance for health in 2022, of which 50-60% was assumed to be allocated for the pharmaceutical sector

Source: Fitch Solutions (2023), IHME database (2023), EPSS procurement data (2020-2023)

Insights

- Manufactures can choose which market they want to primarily serve, ranging from local to global donor markets
- However, the **regulatory approval level** to access each of these markets is **different,** i.e.,
  - the more a company intends to **expand its market size**, the **more** regulatory **requirements** it must meet
- The African export market is highly fragmented with different NRAs for each country, which could make it difficult to scale

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Achieving stringent regulatory approval has many benefits but is costly and makes most sense for manufacturers that can be cost competitive globally

HIGH LEVEL AND NOT EXHAUSTIVE

Benefits

The achievement of WHO-PQ/SRA by manufacturers offers several benefits

- **improved product quality, safety and efficacity**
- **access to donor market** i.e., obtaining WHO-PQ status allows a pharmaceutical product to be procured by donors,
- **accelerated regulatory approvals in other NRA and SRA markets**
- enhanced **credibility and trust** about Ethiopia's capacity to become a **regional hub for manufacturing** quality medicine

Costs	Description	Relative cost
1 **Fees**	Costs associated with the **initial application for prequalification,** and includes fees for single registration, annual fee and post-prequalification changes per Finished Pharmaceutical Product	**$11k – 48k** per new application
2 **TA cost**	Expenses associated with hiring **technical assistants** or **advisory services** to provide expertise in regulatory affairs, quality management, and other relevant areas.	
3 **CAPEX costs**	**CAPEX cost include facility upgrades** and equipment improvements to ensure compliance with GMP standards	**5-15%** of increase in CAPEX
4 **OPEX costs**	**Operational cost** such as utility, labor costs and staff training to ensure ongoing compliance to standards	**15-50%** of increase in OPEX
5 **Opportunity costs**	Manufacturers incur opportunity costs during the WHO-PQ process (~1-3 years) while producing at WHO-PQ standards but not reaping its benefits	

Insights

- WHO-PQ/SRA approval offers several benefits
- Although the WHO-PQ programme has low submission fees, it still has **high hidden costs**
- To offset the high capital investment, manufacturers need to:
  - Produce at **scale**
  - Remain **cost competitive** in the global market
  - Focus on **export market** and **donor market**

Source: WHO website, Expert Interviews

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Local manufacturers are faced with significant barriers to overcome in order to successfully enter the donor market and SRA export market

Difficulty to achieve: High | Medium | Low

	Scenario 1: Strengthening current approach	Scenario 2: Local market at scale (private market)	Scenario 3: Export market at scale and donor market
Regulatory and quality requirements	Manufacturers will have to meet GMP and other EFDA requirements to be able to sell through RDF	The local private sector, in general, tends to be less demanding with regulatory and quality requirements	Manufacturers must meet stringent regulatory standards (WHO-PQ/SRA), which add significant operational costs to their production
Level of competition	Markets are not highly price competitive since RDF products are procured from a limited number of producers and the tenders are either reserved for local producers only or include price preferences	Markets are slightly more price-competitive because products can be procured from multiple producers, including international producers (through importers)	Market is highly price competitive, requiring manufacturers to be cost competitive at a global scale to attract international purchasers
Volume	Manufacturers can therefore produce relatively low volumes	Manufacturers need to produce slightly higher volumes	Successful manufacturers need significant volume to be cost-competitive and to tap into the volumes of both the export market and donor market

- The donor and SRA export markets require both high standards and high volumes
- This requires companies to undertake significant investments over several years (1-3 Y for approval, 3-5Y to achieve operational efficiency).
- This is therefore **not an incremental development**. The industry will not gradually mature from the lower standard, lower volume domestic market to donor and export market without support.
- The government could support by de-risking the market transition with markets shaping instruments, and improving export market attractiveness

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Due to significant barriers, only four SSA manufacturers and no local manufacturers have access to the SRA export and donor markets

	Scenario 1: Strengthening current approach)	Scenario 2: Local market at scale with limited export opportunities	Scenario 3: Export markets at scale and access to donor market
Ethiopian manufacturers	**100%** Of the total 12 medicine manufacturers operate in the Ethiopian market, of which only 2 also export to neighboring countries		**0%** Of local manufacturer has access to the SRA export and donor market
Sub Saharan Africa manufacturers[1]	**99%** Of the total ~375 SSA manufacturers either operate in their local market and export to neighboring countries		**1%** Of SSA manufacturers have achieved WHO-PQ status and have access to this market UNIVERSAL CORPORATION LTD. CiplaQCi aspen HOLDINGS Mylan

1. Not necessarily Sub-Saharan African companies, but manufacturing facilities in the continent (e.g., Mylan)

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SECTION A: Overall key insights and action plan

SECTION B. Demand overview

SECTION C: Regulatory pathways overview

SECTION D: Manufacturers overview

SECTION E: General tablets/capsules business case

SECTION HF Other high-level business cases

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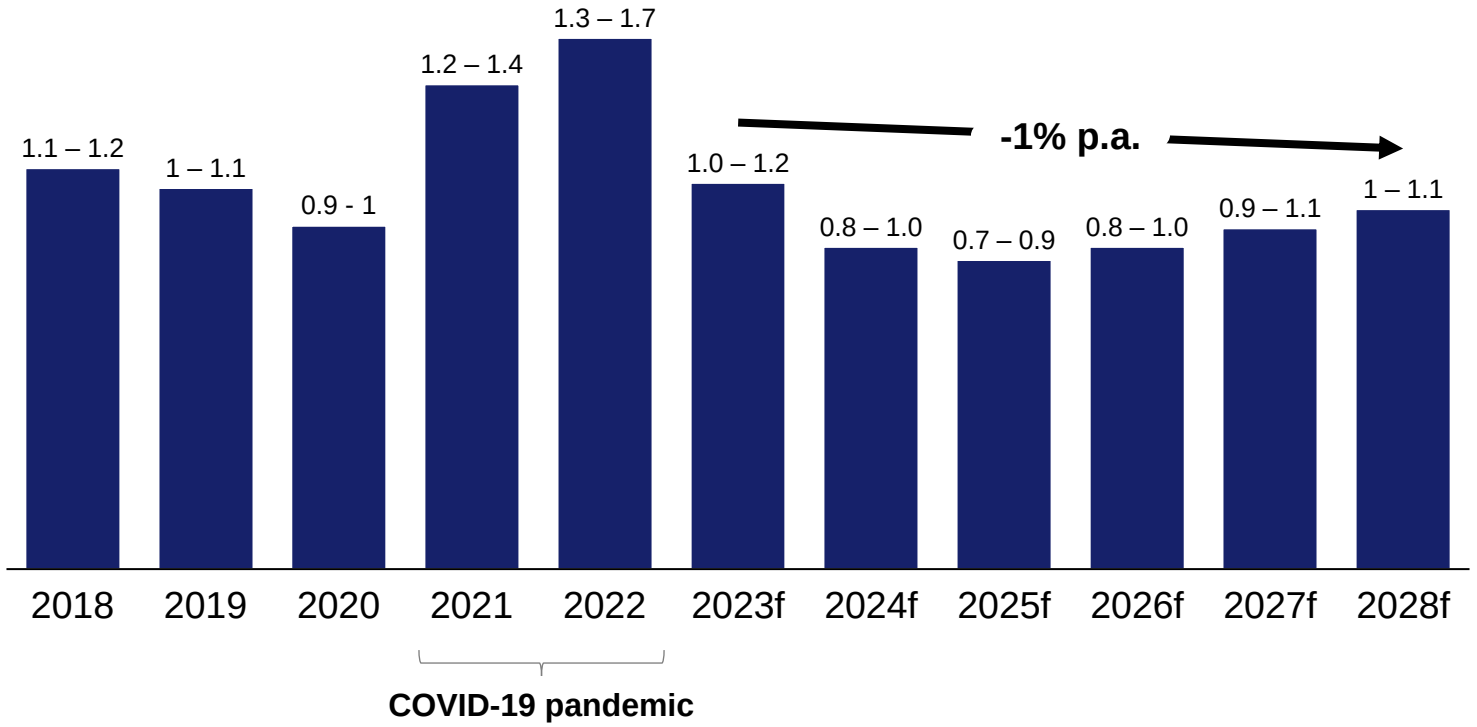
Ethiopia's pharma market is valued at ~1.5$ Bn in 2022, and is expected to slightly decrease due to macroeconomic challenges

Pharmaceutical and medical devices sales[1] (USD billion), historical data and forecasts



NOTE: *While Ethiopia's pharmaceutical market is growing when measured in local currency, the* ***significant devaluation of the birr against the USD****, the* ***high rate of inflation*** *and changes in spending patterns due to the covid-19 pandemic result in the contraction of the market in USD terms.*

1.Medical devices in the Fitch Report include medical equipment and medical supplies. F = forecast.

Source: triangulated from EPSS Procurement data (2020-2023), EIC Pharma Strategy report (2020), Fitch Solutions

Key characteristics

Pharma and medical device sales CAGR (2023f-2028f)	**-1% p.a.**
Number of local pharmaceutical manufacturers	**12**
Number of local pharmaceutical and medical suppliers and manufacturers	**22**
Pharma exports, 2022	**USD 1.15 Mn**

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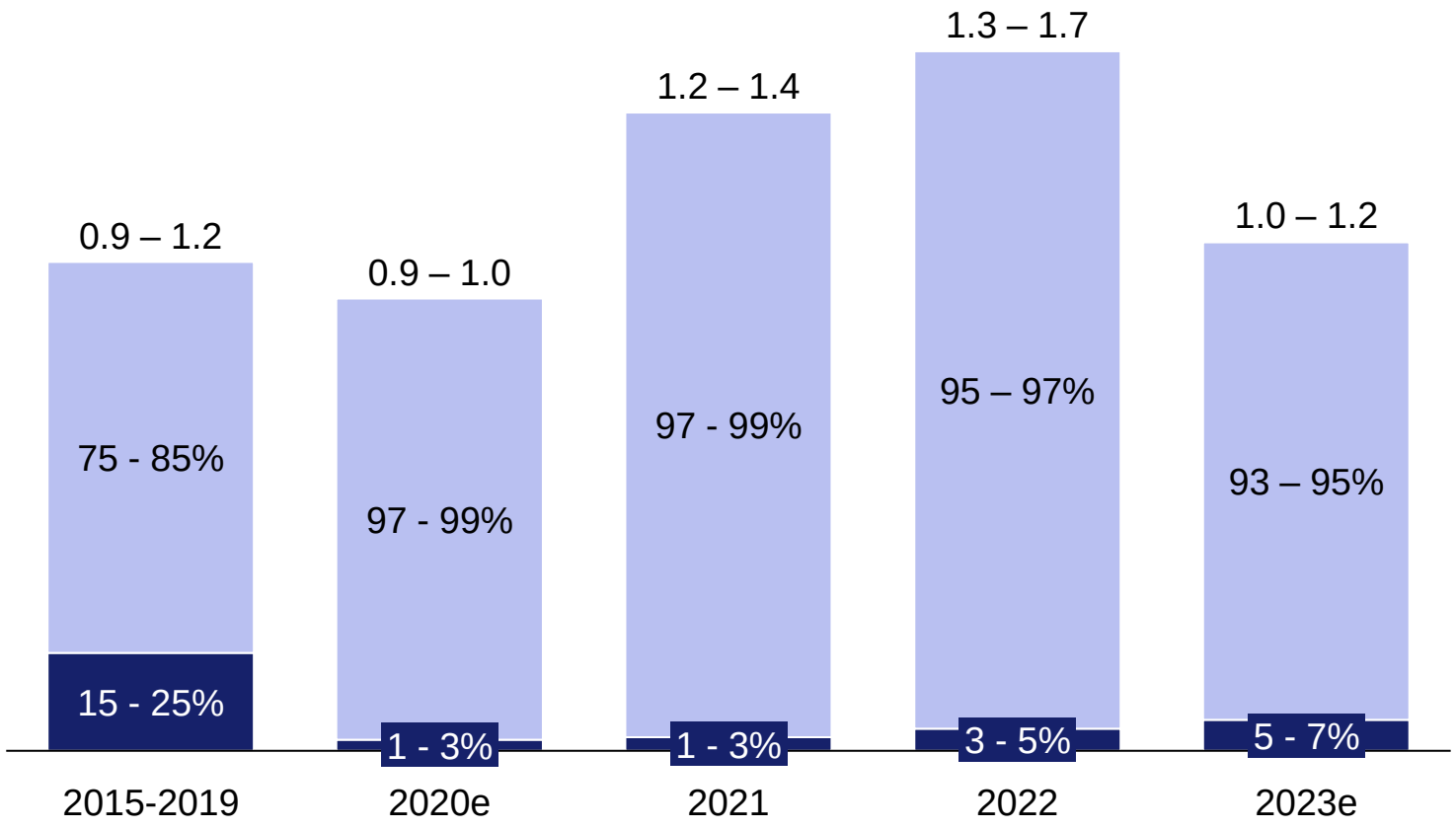

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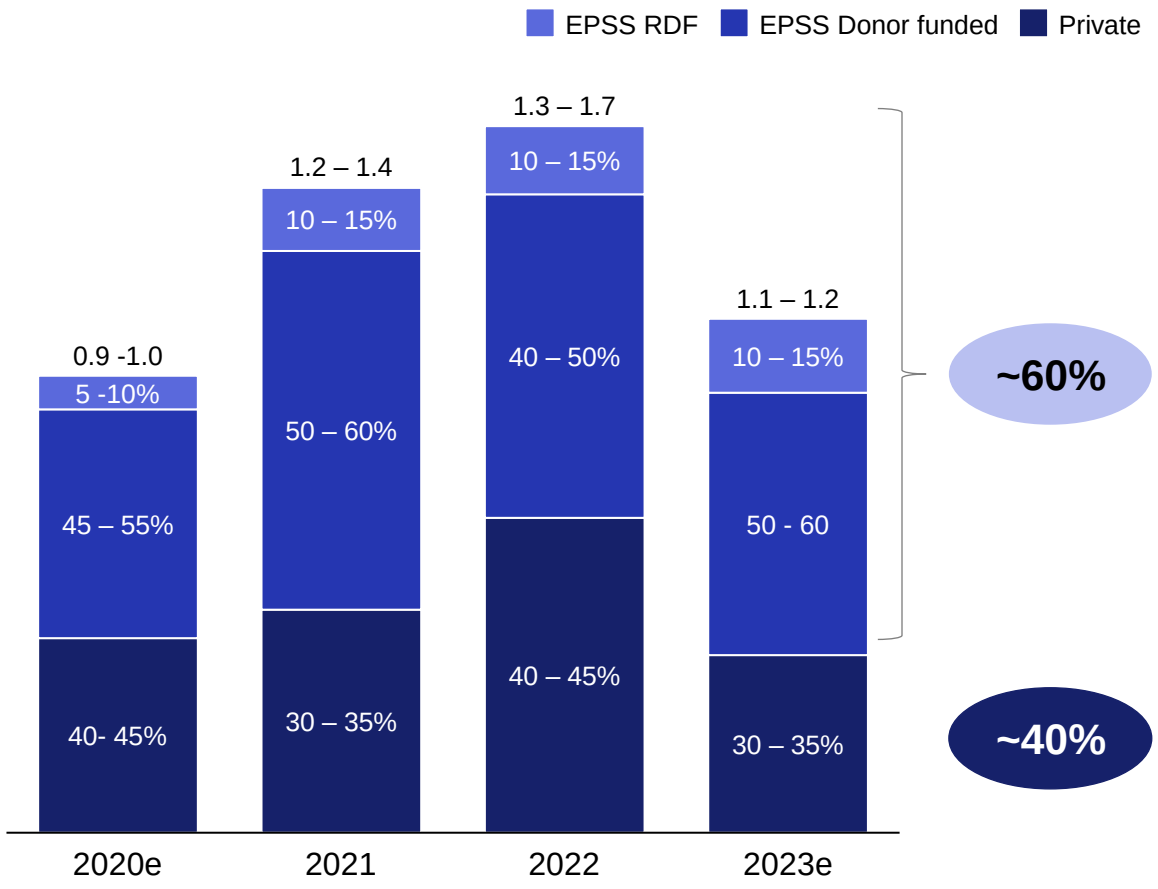
EPSS is the largest purchaser of pharmaceuticals and medical devices in Ethiopia, accounting for ~60% of all procurement

x Public spending out of total, avg

x Private spending out of total, avg

Pharmaceutical and medical devices sales (USD billion)



High level procurementt process

Public and social market

Government purchases through the EPSS Revolving drug fund (RDF)

- Represents ~20% of EPSS procurement on average
- Purchases from both local and international manufacturers
- Offers incentives that serve as protectionist policies for local manufacturers

EPSS purchases funded by donors

- Represents ~80% of EPSS procurements on average
- Purchases mostly from international manufacturers due to high donor regulatory requirements, including WHO-PQ approval for the majority of pharmaceutical products

Private market and individual donor purchases[1]

- Fragmented sector with 10+ mid-sized and 100+ small – sized distributors
- Purchases mostly from the most price competitive manufacturer because of lower regulatory requirements

1. Additional donor purchases are yet to be defined, e.g., USAID

NOTE: For the purpose of this analysis, it is assumed that EPSS spend is in local currency, which was converted to USD. Private sector data was estimated. E=Estimated full year data.
Source: EPSS Procurement data (2020-2023)

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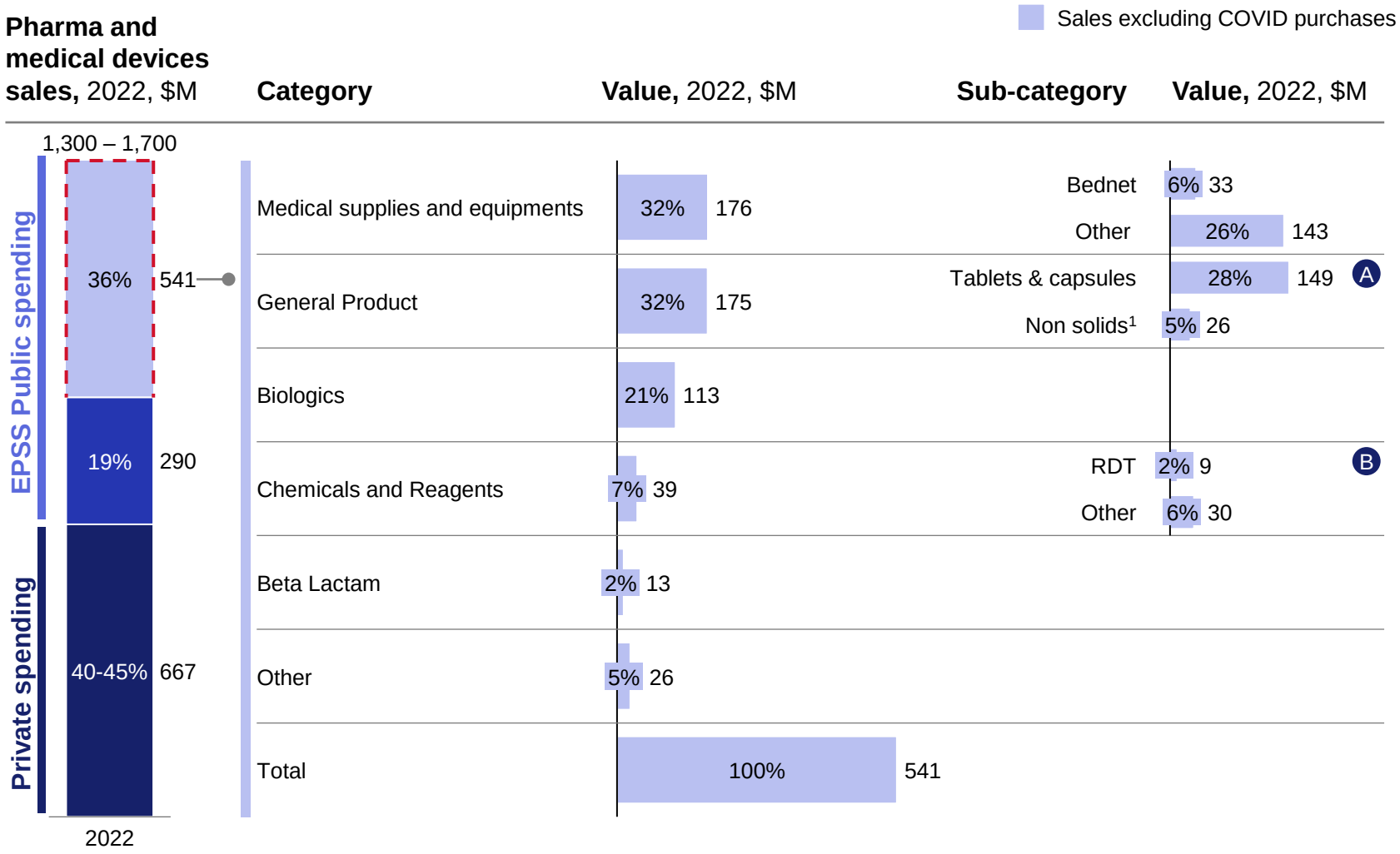
This project centers on tablets/ capsules and RDTs as they underscore manufacturing considerations pertinent to the pharma sector

EPSS procurement data excluding COVID purchases



Rationale

A Tablets and capsules

- Largest category of the pharma products, particularly donor spend
- Existing experience and underutilized capacity in Ethiopia

B RDT

- Lack of local production of RDT in Ethiopia, i.e., the country relies heavily on imports and donations
- Growing market at 12% p.a. in Ethiopia
- High donor interest

1. Nonsolid formulations include liquids and semi-solids

NOTE: For the purposes of this analysis, it is assumed that EPSS spend is in local currency, which was converted to USD. Private sector is not included in the analysis. Source: EPSS procurement data (2020-2023)

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A 6 out of the top 10 tablets and capsules purchased by the EPSS are donor funded products

Deep dive on EPSS procurement data, top 10 tablets/capsules procured

Top 10 tablets/capsules procured	Description	Category	Sales value, 2022, $M	Number of tablets, Mn	Cumulative number of tablets, Mn	Locally sourced by EPSS
1 dolutegravir + lamivudine + tenofovir	Anti-retroviral medicine		33.6	173	173	⊗
2 efavirenz + lamivudine + tenofovir	Anti-retroviral medicine		4.4	23	196	⊗
3 atazanavir + ritonavir	Anti-retroviral medicine		4.1	10	206	⊗
4 artemether + lumefantrine	Antimalarial medicine		3.3	118	324	⊗
5 ethambutol + isoniazid + pyrazinamide+ rifampicin	Antituberculosis medicine		3.1	50	374	⊗
6 doxycycline	Antibiotic medicine		99% 2.1	72	446	✓
7 ferrous salt + folic acid	Antianemia medicine		1.9	264	710	✓
8 metronidazole	Antibiotic medicine		97% 1.8	208	918	✓
9 sulfamethoxazole + trimethoprim	Antibiotic medicine		55% 1.6	94	1,012	✓
10 mebendazole	Intestinal Anthelminthics		66% 1.4	38	1,051	✓
	EPSS Other		92.1	1,199	2,250	⊗
	EPSS Total		149.3	2,250		
	Private market total[1]		186.9	3,220		
	Total		336.2	5,470		

EPSS donor funded RDF

1. Based on an estimate from the value of the private market

NOTE: For the purposes of this analysis, it is assumed that EPSS spend is in local currency, which was converted to USD and the top 95% of the pharmaceutical products was assumed to be representative of the total procurement. Private sector is not included in the analysis. Source: EPSS procurement data (2020-2023)

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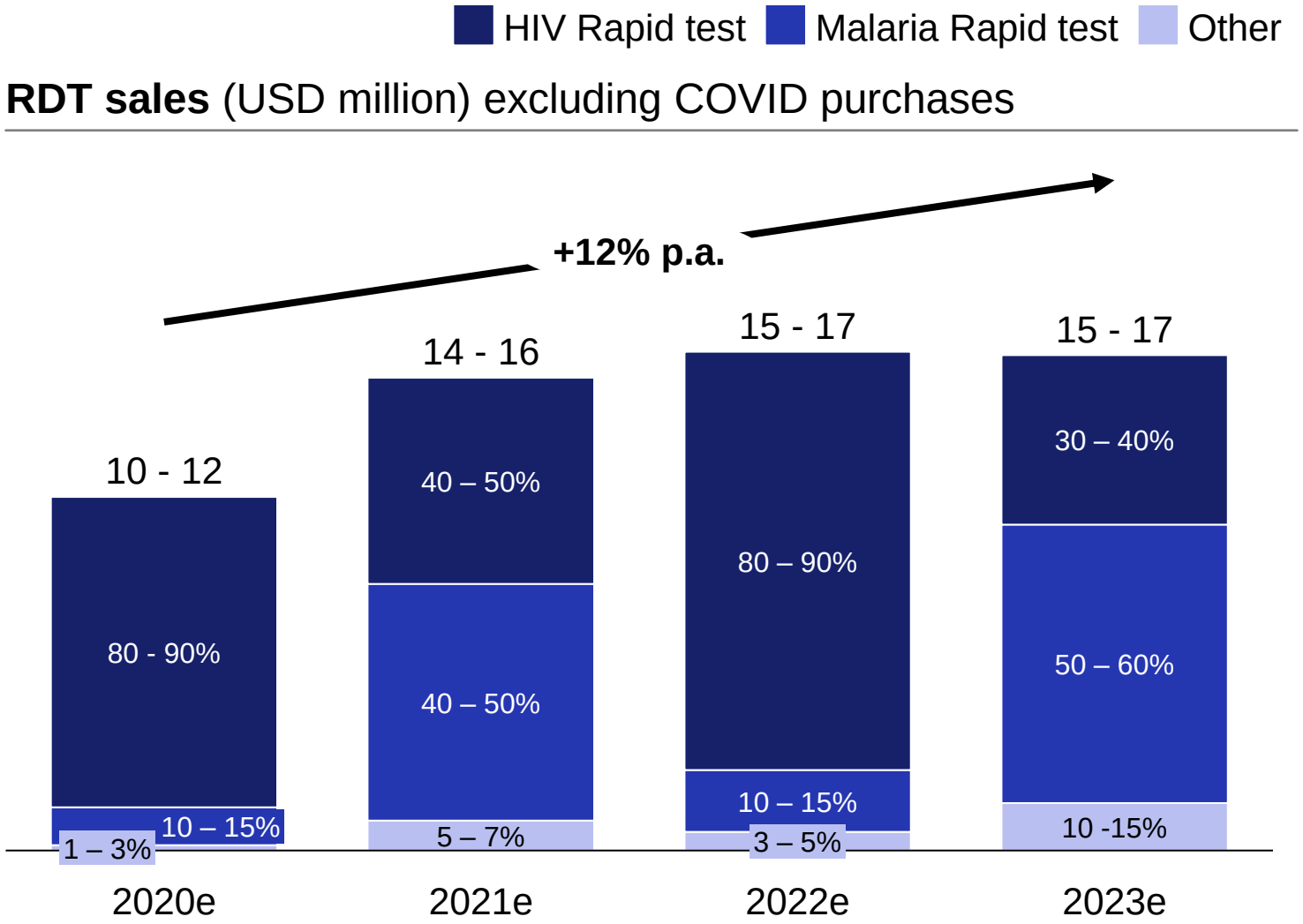
B Ethiopia's RDT market, valued at 16$ Mn in 2022 and growing at 12% p.a., is entirely reliant on imports



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Key characteristics

RDT market CAGR (2020-2023) — **12% p.a.**

Number of RDT types imported in Ethiopia — **7**

Number of local manufacturers supplying RDTs to EPSS — **0**

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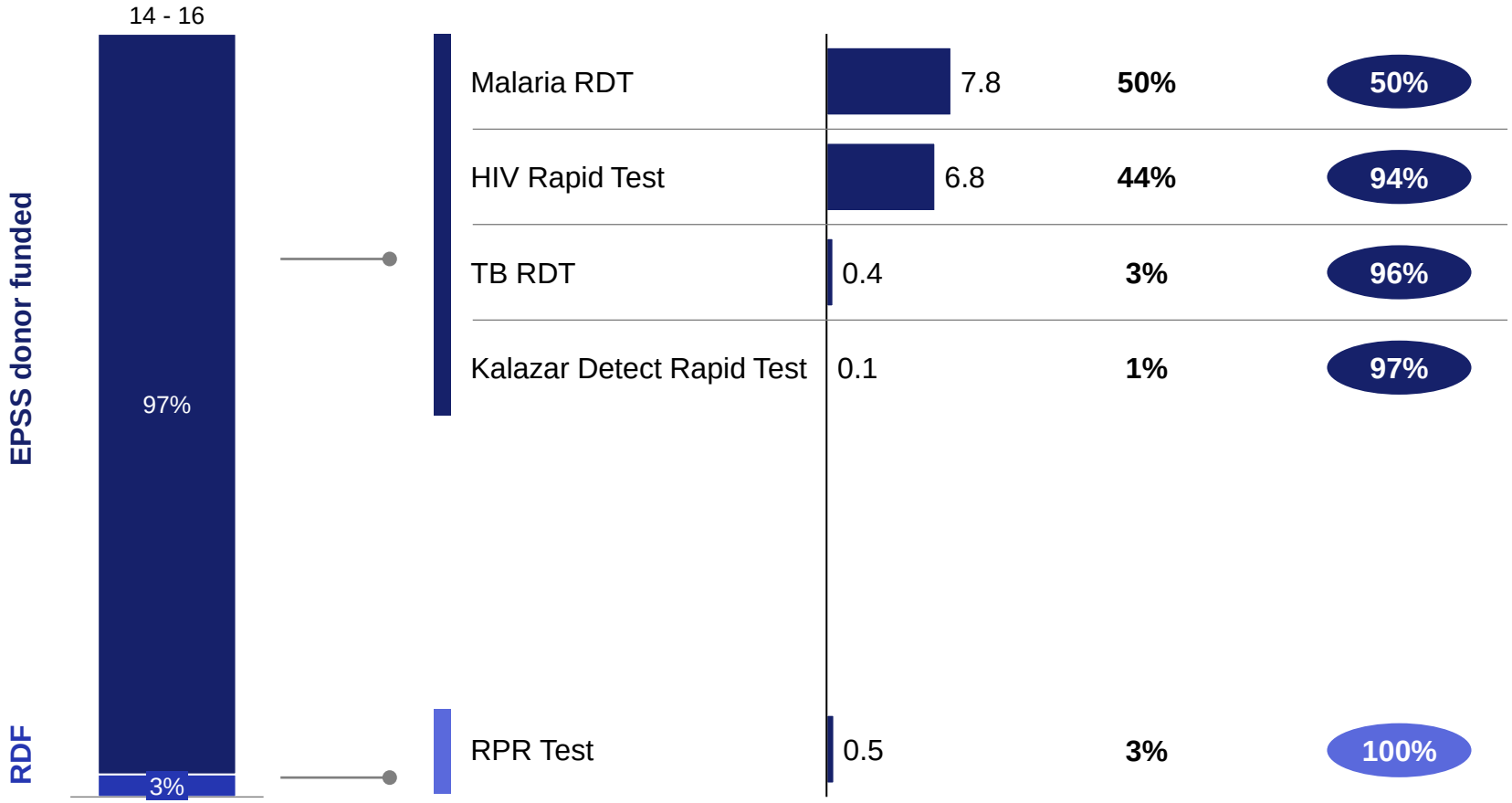
B Donors tend to focus on HIV and Malaria tests, whereas only RPR tests are purchased through the RDF

EPSS procurement data, excluding covid purchases



Source: EPSS procurement data. Note that for the purposes of this analysis, it is assumed that EPSS spend is in local currency, which was converted to USD and private sector data was estimated.

Key insights

- **97%** of RDTs procured were **donor funded** in 2021
- Donors tend to focus on **Malaria and HIV tests**, accounting for 94% of all RDT procurements
- RDTs purchased through the RDF are solely **Rapid Plasma Reagin** (RPR) tests, only accounting for 3% of purchases
- Ethiopia possesses **opportunity to produce RDTs locally** because it currently relies solely on imports and donations

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SECTION A: Overall key insights and action plan

SECTION B. Demand overview

SECTION C: Regulatory pathways overview

SECTION D: Manufacturers overview

SECTION E: General tablets/capsules business case

SECTION HF Other high-level business cases

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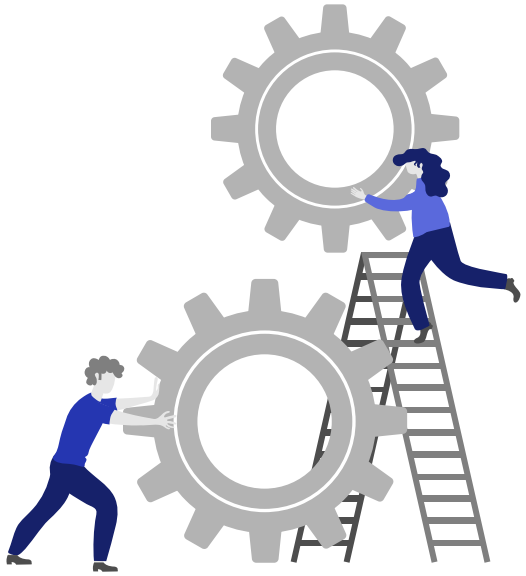
There are overall two levels of regulatory approval



Level	1 Facility level (GMP)	2 Product level
Activity	**Inspection** of the manufacturing and clinical **sites**	Assessment of **product dossiers for finished pharmaceutical products (FPPs)**
Description	Aims to assess and verify compliance of the manufacturer with relevant **good manufacturing practice** (GMP). It ensures that products are consistently produced and controlled according to quality standards	Aims to compile a **master file** that contains all product-related data required to approve the product for **commercial use**. Information on the drug candidate includes chemical composition, pre-clinical and clinical study results, label information and more

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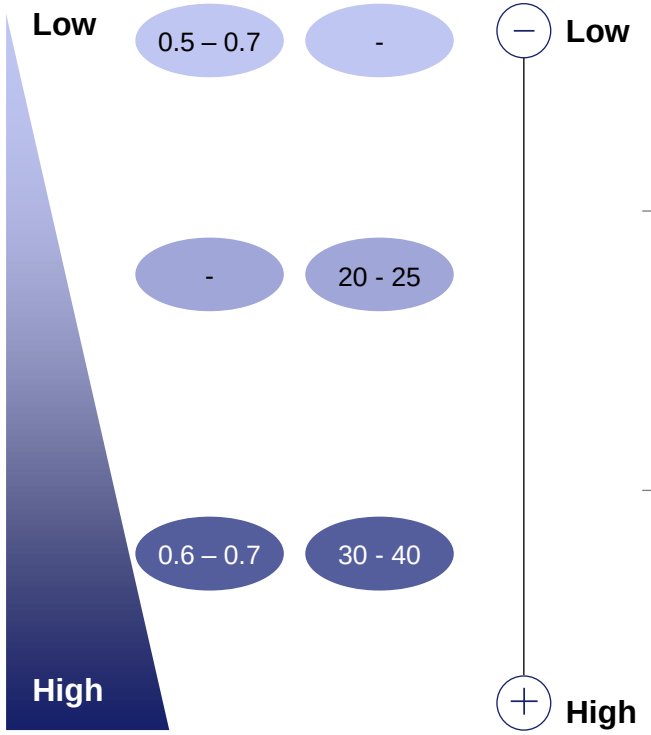
However, to be able to access the large export markets and donor markets, high regulatory requirements must be met

$B, 2022



	Focus market	Description
1	**Local non-donor market**	Manufacturing companies focus on serving the **local non-donor Ethiopian market,** i.e., the public and private sector
2	**Africa non-donor market**	Manufacturing companies focus on **non-donor export markets** to **countries with low regulatory requirements**, i.e. National regulatory authority (NRA) in Africa
3	**Global donor market**	Manufacturing companies focus on serving **donor-funded markets** both locally and globally

Insights

- Manufactures can choose which market they want to primarily serve, ranging from local to global donor markets
- However, the **regulatory approval level** to access each of these markets is **different,** i.e.,
  - the more a company intends to **expand its market size**, the **more** regulatory **requirements** it must meet
- The African export market is highly fragmented with different NRAs for each country, which could make it difficult to scale

NOTE: 1. Ethiopian pharma market size in 2022 is worth ~$1.5Bn, of which 45% is estimated to be donor funded. 2. African pharma market is worth ~$35Bn in 2022, of which 30-40% is estimated to be donor funded. 3. Donor market size was extrapolated using the global ~57Bn of development assistance for health in 2022, of which 50-60% was assumed to be allocated for the pharmaceutical sector

Source: Fitch Solutions (2023), IHME database (2023), EPSS procurement data (2020-2023)

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Manufacturers can consider different regulatory pathways for pharmaceutical product approval

PRELIMINARY AND NOT EXHAUSTIVE

1 Local market 2 Non regulatory stringent markets 3 Donor Market

Main considerations

- Different markets require different regulatory approvals
- Different products require different regulatory approvals
- Every product requires market authorization by the NRA in which the product will be used

Regulatory pathway	Description	Products	Use case
WHO / UNFPA	• Evaluates applications from manufacturers to determine whether their products **meet its standards of quality, safety, and efficacy**	• Vaccines (144+), Medicines (500+ FFPs, 100+ APIs), Diagnostics (80+) and vector control products (70+)	2 Accelerates access to NRA export market 3 Provides access to donor market
SRA / WLA	• Stringent Regulatory Authority such as the US FDA[1] ensures that products **meet standards of quality** and is widely recognized by the international regulatory and procurement community.	• Pharmaceutical products that don't have WHO-PQ	2 Accelerates access to NRA export market 3 Provides access to donor market
Expert Review Panel (ERP)	• ERP is an independent technical body hosted by the WHO that ensures products **meet the eligibility criteria** • ERP can only be leveraged for **urgent needs** of a product that is not yet WHO-prequalified or SRA-authorized, and only lasts 1 year[2]	• Exceptional pharmaceutical products e.g., diagnostic products	3 Provides temporary access to donor market for urgent needs
NRA (non-SRA)	• National Regulatory Authority, it only ensures that products **meet local standards of quality, safety and efficiency,** and provides local market authorization	• All pharmaceutical products	1 Provides access to local market
Regional (African Medicines Agency, AMA)	• AMA evaluates medical products, reviews clinical trials, and aims to **harmonize standards and regulations** in member African countries	• -	2 Accelerates access to export market, i.e., AMA member countries

1. Other examples of SRA include the European Medicines Agency (EMA), Health Canada, and the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan 2. The ERP's recommendation is valid for a period of no more than 12 months or until the products is WHO-prequalified or SRA-approved, whichever is the earlier

Source: Global Fund ERP Process; UNFPA PQ overview; WHO incorporation of USFDA and EMA approval

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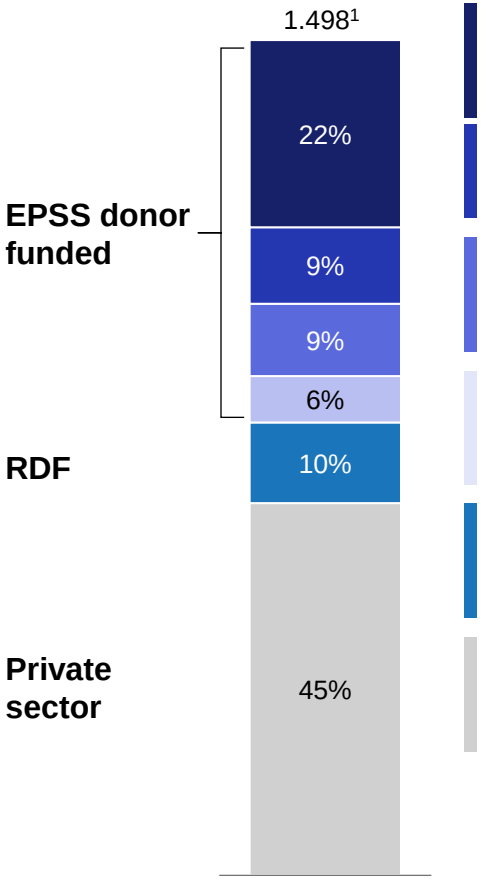
Majority of pharma products purchased are donor funded and have high regulatory requirements

EPSS procurement data

Pharma and medical devices sales, 2022, $M



Donors	Regulatory requirements	Comment
UNICEF	WHO-PQ / SRA	UNICEF self-procures its top products including HPV vaccine, pentavalent vaccine and Rota Virus vaccine
Global Fund	• WHO-PQ / SRA • ERP	Funds are transferred to EPSS, who runs the procurement process for its top products including TLD and mosquito bed nets
Private corporate donations	Donations could be specific branded products	Companies' self procure products. Top products include Azithromycin as part of the Trachoma Initiative and Ivermectin
Other	WHO-PQ / SRA	Other funds include SDG, Gavi, UNFPA, etc. that either self procure or transfer funds to EPSS
RDF	EFDA	Starting from June 2024, all local manufacturers are required to achieve EFDA GMP approval at facility level
Private sector	EFDA	-

1. 1.498 is the total value of pharma sales in Ethiopia, of which $149 M represents tablets/capsules procured buy EPSS

NOTE: For the purposes of this analysis, it is assumed that EPSS spend is in local currency, which was converted to USD. Private sector is not included in the analysis. Source: EPSS procurement data (2020-2023)

Insights

- **45%** of pharma products procured in the country were purchased through **donor funded programs** in 2022
- Most international procurement agencies have **high regulatory requirements,** and procure products that have been either:
  - Prequalified by the WHO Prequalification Programme
  - Authorized for use by a Stringent Regulatory Authority
  - Recommended for use by the Expert Review Panel
- **Achieving WHO-PQ** status is a **requirement** for local manufacturers to **access donor market**
- However, **obtaining WHO-PQ doesn't guarantee access to donor funds** because, depending on the agreements in place (procurement rules/requirements), some donors may have an influence on the **selection of manufacturer or** may **self-procure** the products

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Core regulatory agency functions have similar functions with four major regulatory milestones

NON-EXHAUSTIVE

Processes may vary and occur at multiple levels – see next page for additional deep dive

Key regulatory functions	Clinical Trial Authorizations	Reg. and tech standards	GMP inspections[2]	Scientific advice and dossier assessments (including variations)	Local market authorization	Safety & PV	Emergency authorizations

Regulatory milestones	Inputs	**Release of regulatory and technical standards / guidelines**	**Scientific assessment / approval**	**Market authorization**	**Ongoing monitoring**
Key activities		**Collect and evaluate clinical evidence** (e.g., clinical trial data, lab testing) **Write regulatory and technical standards / guidelines**	**Ensure compliance** with standards and guidelines by **conducting facility inspections** and **evaluating manufacturing processes** (e.g., GMP inspection) **Write scientific advice**	**National registration** of approved product	**Collect and monitor long-term safety and efficacy** of products **Conduct ongoing facility inspections** to ensure GMP compliance
Outputs		**Manufacturing specifications and clinical guidelines** for product development that define **a "checklist" of requirements** for scientific approval	**Certificate of scientific approval** for a given manufacturer of a specific medical product	**Market-specific approval** for sale of manufacturer's product	**Approval for manufacturers** to continue to sell products

Cross-cutting activities	
	Monitoring in case of emergency authorization need
	Collaboration between regulatory bodies (e.g., regulatory systems strengthening[1] and harmonization of guidelines and technical standards)

1 Core tenet of WHO work
2 Included in both scientific assessment / approval and ongoing monitoring

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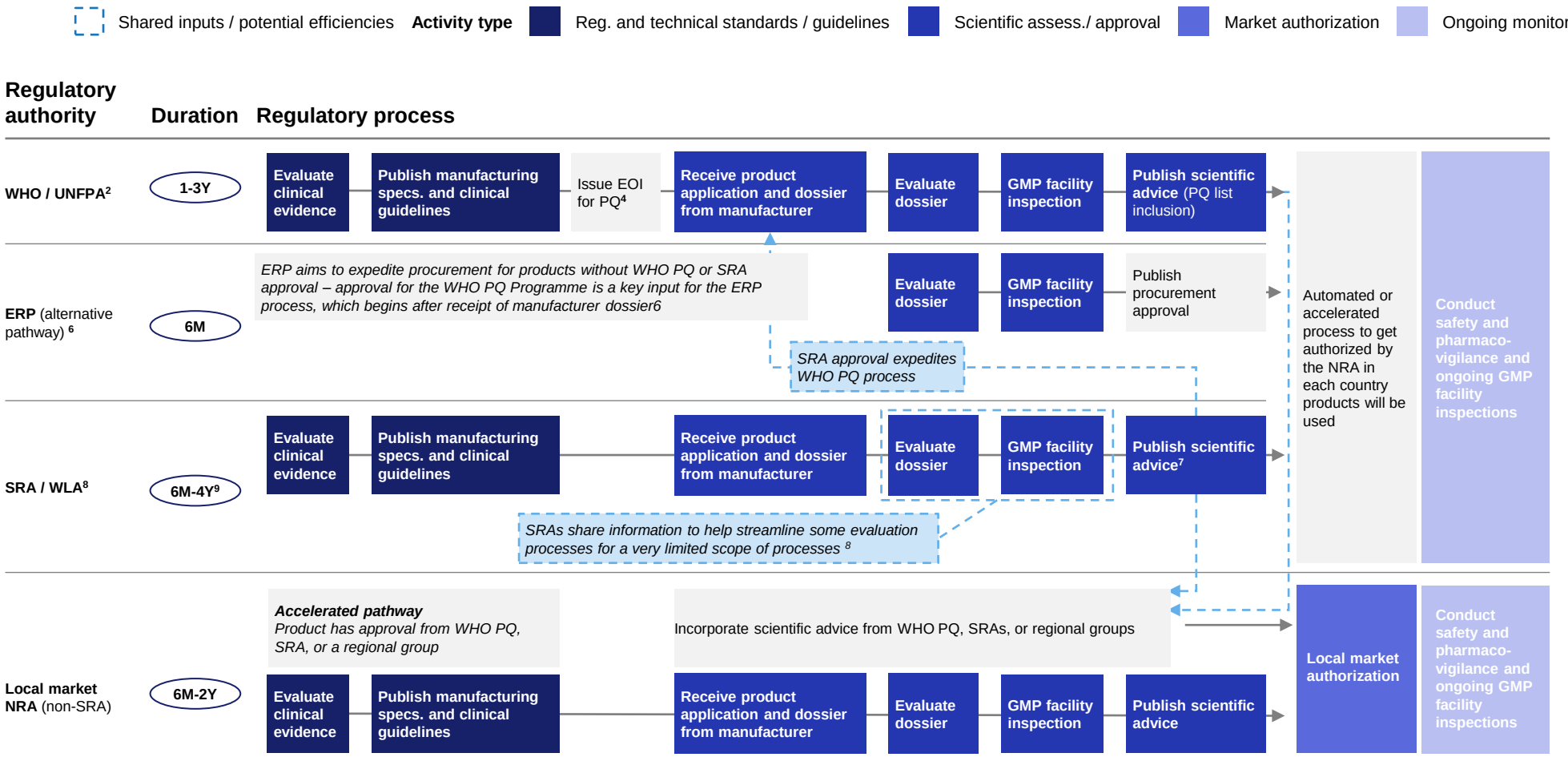
Although the current regulatory process for the various pathways is similar, the level of scrutiny varies and is higher for WHO-PQ and SRA



Insights

- The different pathways have a **similar regulatory process**
  - WHO/SRA and ERP do not grant market authorization in the local market, but they can **accelerate the process.**
- The **level of scrutiny** for each regulatory pathway **varies**
  - SRA and WHO-PQ program have a higher level of scrutiny

1. Includes US, Japan, Canada, Australia, Switzerland, Liechtenstein, Norway, and Iceland; 2. WHO manages PQ programmes for IVDs, Medicines, Vaccines and Immunization Devices, Vector Control; UNFPA manages the prequalification programmes for male latex condoms, female condoms and copper TCu380A IUDs.; 3. Certificate of good manufacturing practice certificate issues by a SRA, a members of PICs, or WHO PQ GMP compliance; 4. Expression of Interest; 5. Approval is limited to only 12 months or until WHO PQ or SRA approval; 6. The ERP is operationally managed by GFATM, but development of procedures and criteria and product evaluation are conducted by WHO; 7. EMA submits opinion to European Commission; 8 Example: EMA and FDA have had data sharing agreements in place since 2003 to help streamline assessment processes (e.g., EMA does not require batch testing for products that have been batch test approved by the FDA) 9. Based on FDA approval duration, for which site inspection takes 3-12 months and drug approval process can take 6-10 months

Source: Global Fund ERP Process; UNFPA PQ overview; WHO incorporation of USFDA and EMA approval

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Achieving stringent regulatory approval has many benefits but is costly and makes most sense for manufacturers that can be cost competitive globally

HIGH LEVEL AND NOT EXHAUSTIVE

Deep dive to follow

Benefits

The achievement of WHO-PQ/SRA by manufacturers offers several benefits

- **Improved product quality, safety and efficacity**
- **access to donor market** i.e., obtaining WHO-PQ status allows a pharmaceutical product to be procured by donors,
- **accelerated regulatory approvals in other NRA and SRA markets**
- enhanced **credibility and trust** about Ethiopia's capacity to become a **regional hub for manufacturing** quality medicine

Costs	Description	Relative cost
1 **Fees**	Costs associated with the **initial application for prequalification,** and includes fees for single registration, annual fee and post-prequalification changes per Finished Pharmaceutical Product	**$11k – 48k** per new application
2 **TA cost**	Expenses associated with hiring **technical assistants** or **advisory services** to provide expertise in regulatory affairs, quality management, and other relevant areas.	
3 **CAPEX costs**	**CAPEX cost include facility upgrades** and equipment improvements to ensure compliance with GMP standards	**5-15%** of increase in CAPEX
4 **OPEX costs**	**Operational cost** such as utility, labor costs and staff training to ensure ongoing compliance to standards	**15-50%** of increase in OPEX
5 **Opportunity costs**	Manufacturers incur opportunity costs during the WHO-PQ process (~1-3 years) while producing at WHO-PQ standards but not reaping its benefits	

Insights

- WHO-PQ/SRA approval offers several benefits
- Although the WHO-PQ programme has low submission fees, it still has **high hidden costs**
- To offset the high capital investment, manufacturers need to:
  - Produce at **scale**
  - Remain **cost competitive** in the global market
  - Focus on **export market** and **donor market**

Source: WHO website, Expert Interviews

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Hidden OPEX costs are significantly because manufacturers need to adopt a wide range of activities to attain WHO-PQ status

PRELIMINARY AND NOT EXHAUSTIVE

Theme	Activity	Description
People	Training and skill development	Employee training is needed to implement the **WHO's Good Manufacturing Practices (GMP**) and other relevant guidelines including quality control, quality assurance, documentation practices, and compliance requirements etc.
	Hiring skilled professionals	Professional who can develop, implement, and oversee **quality management systems** are needed to ensure compliance with WHO standards.
Machinery	Maintenance and calibration of equipment	Regular **validation and calibration of machinery** is necessary to ensure consistency and reliability in the manufacturing process, and meet WHO standards
Quality control	Quality control testing	Regular quality control **testing of medicines** (FPPs and APIs) are needed
Data collection	Documentation and record keeping	Frequent documentation is needed to maintain comprehensive records of manufacturing processes, quality control measures etc.
Compliance audits	Conduct internal and external audit	Ensure **ongoing compliance** with WHO standards through **audits,** that may uncover areas of improvement leading to additional investments to address the gaps

Key takeaways

- Manufacturers must invest in **people, processes** and **machinery to** meet the stringent quality standards set by the WHO
- These investments are crucial not only for obtaining certification but also for **maintaining a high level of quality assurance** and **compliance** over time

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Although WHO PQ provides access to the donor market, only a few SSA manufacturers have achieved WHO PQ status (1/2)

Companies with WHO prequalification status (as of Nov 2023)

Top program drugs purchased by EPSS

Company[1]	Country	Prequalified product(s) , excluding vector control products
UNIVERSAL CORPORATION LTD.	Kenya	1 Lamivudine/Zidovudine 2 Dolutegravir (Sodium)/Lamivudine/Tenofovir 3 Artemether/Lumefantrine 4 Pyrimethamine/Sulfadoxine
CiplaQCi	Uganda	5 Lamivudine/Zidovudine 6 Lamivudine/Tenofovir 7 Efavirenz 8 Efavirenz/Lamivudine/Tenofovir 9 Dolutegravir (Sodium)/Lamivudine/Tenofovir 10 Artemether/Lumefantrine 11 Isoniazid/Pyridoxine hydrochloride/Sulfamethoxazole/ Trimethoprim
aspen HOLDINGS	South Africa	12 Lamivudine/Zidovudine
atomo Mylan	South Africa	13 HIV rapid self-test

Additional medicines for which SSA manufacturers are pursuing WHO-PQ approval for include:

1. Albendazole 2. Amoxicillin DT 3. Artemether Lumefantrine 4. Azithromycin 5. Isoniazid (API) 6. Magnesium Sulfate 7. Mebendazole 8. Oxytocin 9. Sulfadoxine Pyrimethamine 10. Zinc Sulfate

Insights

- Among the ~375 manufacturers, only **4 SSA companies** have achieved WHO pre-qualification status (as of Nov 2023)
- There are currently **13 product lines** that are pre-qualified for **donor procurement** in SSA, of which 6 of them are part of the top program drugs purchased by the EPSS
- Currently, **EPSS does not purchase any of these program products** from any of the manufacturers listed
- This trend reflects the need for local manufacturers to achieve WHO-PQ while **remaining cost competitive**

1. Manual search for all companies with medicines with active status in WHO Prequalification medicines list for FPP, API and In Vitro Diagnostic Products

Source: WHO Pre-qualification list (accessed as Nov 2023)

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Although WHO PQ provides access to the donor market, only a few SSA manufacturers have achieved WHO PQ status (2/2)

Deep dive on SSA manufacturers who have achieved WHO-PQ status

Company[1]	Country	Year of Establishment	**Manufacturing capacity,** M tablets per year	Description
UNIVERSAL CORPORATION LTD	Kenya	1996	1,000	• Produces more than 100 formulations, and is specialized in producing HIV/AIDS and malaria drugs • Supplies medicine to international organizations such as **UNICEF**, **USAID**, and other donors throughout Kenya and more than 10 African countries
CiplaQCI	Uganda	2005	1,500	• Joint venture between Cipla, QCI and the **government of Uganda** • Specialized in producing medicines to treat HIV/AIDS and malaria • Currently exports to 13 countries in Africa and 2 in Southeast Asia, and sells majority of its products to local and export **governments,** either directly or through the **Global Fund**
aspen HOLDINGS	South Africa	1997	13,700	• **Largest pharmaceutical company** in Africa, operating 23 manufacturing facilities spread across more than 10 countries • Produces a wide range of product types, including FPPs, APIs and biologicals • Holds **international manufacturing approvals** from SRAs including, the US FDA and the European Directorate for the Quality of Medicines.
Mylan	South Africa	1961	N/A	• Produces a wide range of products, including FPPs and APIs, and is the **leading supplier of ARV to the South African government** • Merged with Upjohn, Pfizer's off-patent medicine division to form Viatris in 2020

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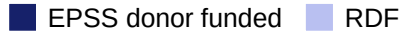
In Ethiopia, 2 local manufacturers have done early stage WHO-PQ inspection for 3 pharma products



Manufacturer	Product	Description	**EPSS Procurement value,** 2022, $M	**Procurement volume**, Mn tablets	**Price per tablet,** $	Category
Sansheng Pharmaceutical PLC	**Mebendazole** tablet	Anti-infective medicine	1.4	38.5	0.0143 For 500mg	
	Fluconazole capsule	Anti-infective medicine	0.3	4.7	0.0582 For 200mg	
Humanwell Pharmaceutical Ethiopia PLC	**Magnesium sulfate,** 50% injection	Medicines for disease of the nervous system	1.6	N/A	N/A	

Kilitch and Glocare are currently under the process of obtaining an **SRA GMP compliance** from an EU member state, which would give automatic GMP compliance to all SRA markets. They jointly **received technical assistance** from an **independent QP inspector** (Qualified Person).

Source: EPSS Procurement Data (2020-2023)

Context and potential rationale

- Ethiopian local demand for these products is **low**
- Manufacturers intend to **export the products** in SSA
- Both manufacturing facilities are relatively **new** and are **EFDA GMP approved**
- Both have **Chinese partners through their joint ventures,** and Kilitch an Indian partner, who have experience with the WHO PQ programme

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Key takeaways

1. The WHO-PQ regulatory pathway is a **manufacturer-led process**, that requires **strategic decision-making** by the manufacturer to **maximize the benefits** of achieving WHO-PQ status

2. WHO-PQ pathway doesn't offer economic incentives for local manufacturers that primarily focus on **serving the local non-donor market**

3. WHO-PQ is **particularly relevant** for:
   - **Companies** with the capacity to manufacture and distribute pharmaceutical products for **exports at scale**
   - **Products** that are donor-funded through health programs
   - **Companies** with relatively **modern** manufacturing lines, and who have **experience** with the WHO PQ programme through their partnerships

4. The increase of Ethiopian manufacturers achieving WHO-PQ status will have a broader **impact on the wider pharmaceutical ecosystem**

5. The Government of Ethiopia could potentially accelerate this process by **leveraging donor funds strategically**

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NOT-EXHAUSTIVE

There are concrete actions that development partners and MoH can take speed up the process and increase success rate in Ethiopia

- Promote and provide training for manufacturers on GMP practices
- Promote the realization of Q&A sessions with WHO and SRA regulators on regulatory approval inquiries
- Sponsor and organize comprehensive technical assistance programs for manufacturers on GMP, QMS and other regulatory gaps
- Promote collaboration between manufacturers in registration procedures to encourage different manufacturers go through this process jointly

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Ethiopia's local manufacturing ecosystem has progressively grown overtime, primarily driven by strategic joint ventures with international partners

Rise of local pharmaceutical manufacturing

1964

EPHARM E-PHARM was founded in 1964 as a joint venture between the **Ethiopian government** and a British company, and it was nationalized in 1975 before being privatized in 2014

Subsequent boom through strategic joint ventures

1990

APF APF was established in 1992 by a joint venture of an Ethiopian company with a **British manufacturer.** APF is the **largest pharma manufacturing company** and was heavily affected by the conflict in Tigray

East African Pharmaceuticals PLC East African was founded in 1996 as a joint venture between **British and Sudanese companies**

PLC Pharmacure was founded in 1998 as a private **Ethio-Saudi investment**

MedSol Pharmaceuticals Medsol was established in 1999 as a fully **Ethiopian private player**

CADILA PHARMACEUTICALS LIMITED Cadila was established by a **joint venture of an Ethiopian company and an Indian manufacturer** in 2003

Reform and revival period

2013

Julphar Julphar was established in 2013 as a **joint venture with a UAE company**

Humanwell Pharmaceuticals PLC Humanwell was established in 2016 as the **first independent Chinese investment** in Ethiopia's pharma sector

SSP Sansheng was founded in 2018 as an **independent Chinese investment,** and is the first local pharma manufacturer to receive EFDA GMP approval

KKE Kilitch was established in 2020 by a **joint venture of an Ethiopian company and an Indian** Pharma manufacturer

Glocare was founded in 2022 as the **first independent Indian investment** in Ethiopia's pharma sector

africure **Trust Pharma** + 2 pharma companies are expected to **enter the market in 2024**, namely **Africure (JV)** and **Trust Pharmaceuticals (Ethiopian private player)**

Source: Market research, company websites, interviews

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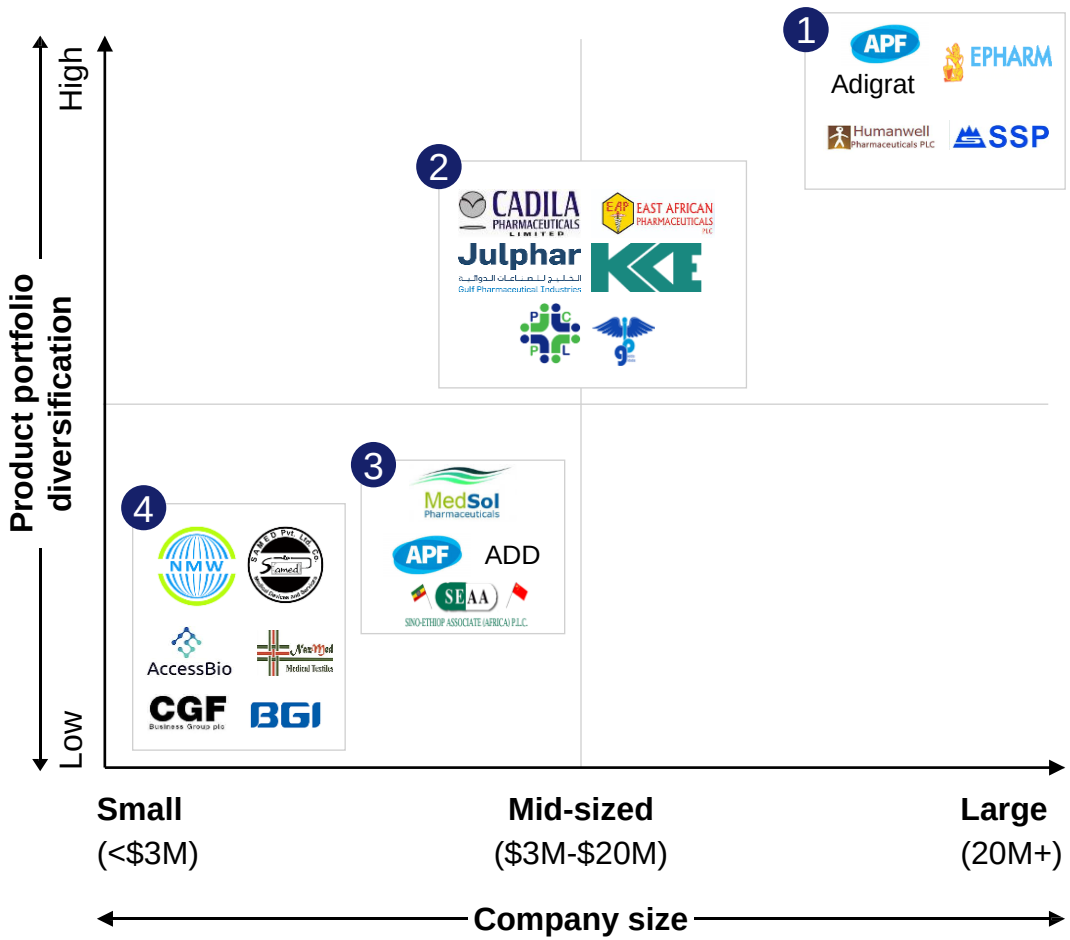
Local manufacturers generally could be categorized into four main archetypes based on their size and product portfolio diversification

PRELIMINARY **ILLUSTRATIVE / NOT EXHAUSTIVE**

Ethiopian local manufacturer landscape



Archetypes		Description	Manufacturer
1	**Large pharma players**	Initial investment of over **$ 20M,** production capacity of > **1B** tablets & capsules per year, and with > **60** different types of products	Adigrat, EPHARM, Humanwell Pharmaceuticals PLC, SSP
2	**Mid-sized diversified pharma players**	Mid-sized manufacturers with an initial investment of **$3 – 20M,** with **30-50** different types of products on average	CADILA PHARMACEUTICALS LIMITED, EAST AFRICAN PHARMACEUTICALS, Julphar, Gulf Pharmaceutical Industries, KKE
3	**Small specialized pharma players**	Small sized **(< $ 2M)** specialized players focused **<5 products**	MedSol Pharmaceuticals, APF, ADD, SEAA, SINO-ETHIOP ASSOCIATE (AFRICA) P.L.C.
4	**Other non pharma**	Manufacturers focused on production of **non pharma products** such medical supplies and devices	NMW, Samed, AccessBio, Medical Textiles, CGF Business Group plc, BGI

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There are currently 12 pharmaceutical manufacturers in Ethiopia, excluding those producing medical supplies and devices

Company	Owner-ship	Establish-ment year	Initial I, $M	Number of products	Number of manufac-turing lines	Product type		
						Beta lactams	General - Tablet/capsule	General - Other
E-PHARM		1964	20	92	8	✓	✓	✓
APF – Adigrat		1992	65	74	8	✓	✓	✓
APF – Addis Ababa		1992	65	4	1	✗	✗	✓
East African		1996	3	31	2	✗	✓	✗
Pharmacure		1998	10	4	1	✗	✗	✓
Medsol		1999	N/A	4	1	✗	✗	✓
Cadila		2003	10	54	3	✗	✓	✓
Julphar		2013	9	25	3	✗	✓	✓
Humanwell		2016	21	88	4	✗	✓	✓
Sansheng		2018	85	63	5	✗	✓	✓
Kilitch		2020	12	32	4	✓	✗	✓
Glocare		2022	6	38	2	✗	✓	✓

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Existing manufacturers typically have suboptimal production levels, and only 5 of the 12 meeting local GMP requirements

Company		Capacity[1], M	Current Utilization	Regulatory approvals: EFDA cGMP approved[2]	Regulatory approvals: Started African NRA process	Regulatory approvals: Started WHO/SRA process	Comment
EPHARM	E-PHARM	1,000	<25%	✗	✗	✗	Has a green field project to build a **brand-new pharmaceutical factory** that meets GMP standards, and interested in pursuing WHO-PQ
APF	APF – Adigrat	N/A	N/A	✗	-	-	-
APF	APF – Addis Ababa	0	N/A	✗	-	-	-
EAST AFRICAN PHARMACEUTICALS	East African	N/A	N/A	✗	-	-	-
PCPL	Pharmacure	0	<50%	✗	✓	✗	Has a green field project to build a **brand-new penicillin production plant** that meets GMP standards, with a **capacity of 1.3 Bn** tablets and capsules and interested in pursuing WHO-PQ
MedSol Pharmaceuticals	Medsol	0	N/A	✗	-	-	-
CADILA PHARMACEUTICALS LIMITED	Cadila	N/A	N/A	✓	✓	✗	Abandoned the WHO-PQ pathway due to cost and time but is interested in African NRA pathways
Julphar	Julphar	500	<20%	✗	✗	✗	Has a green field project to build a **brand-new production plant** that meets GMP standards, and is interested in pursuing SRA GMP compliance from MHRA[3]
Humanwell Pharmaceuticals PLC	Humanwell	1,600	<30%	✓	✓	✓	Is pursuing WHO-PQ for **Magnesium sulfate 50% injection**, received TA from the WHO-PQ team **supported by the MOH**
SSP	Sansheng	5,000	<15%	✓	✓	✓	Is pursuing WHO-PQ for **Mebendazole and Fluconazole**, received TA from the WHO-PQ team **supported by the MOH**
KKE	Kilitch	500	<10%	✓	✓	✓	Manufactured **products do not require WHO-PQ,** therefore is interested in **SRA GMP compliance** ideally from an EU member state, received TA from an independent QP inspector
	Glocare	600	N/A	✓	✓	✓	Is interested in **SRA GMP compliance** from an EU member state. Received TA from an independent QP inspector (Qualified Person) jointly with Kilitch

1. Production capacity per 24h shift for tablets and capsules
2. As part of the national Good manufacturing Practice (GMP) roadmap to guide manufacturer's progress towards meeting international standards, all local manufacturers are required to achieve EFDA GMP approval by 2024
3. Medicines and Healthcare products Regulatory Agency (MHRA) is the regulatory authority in the UK

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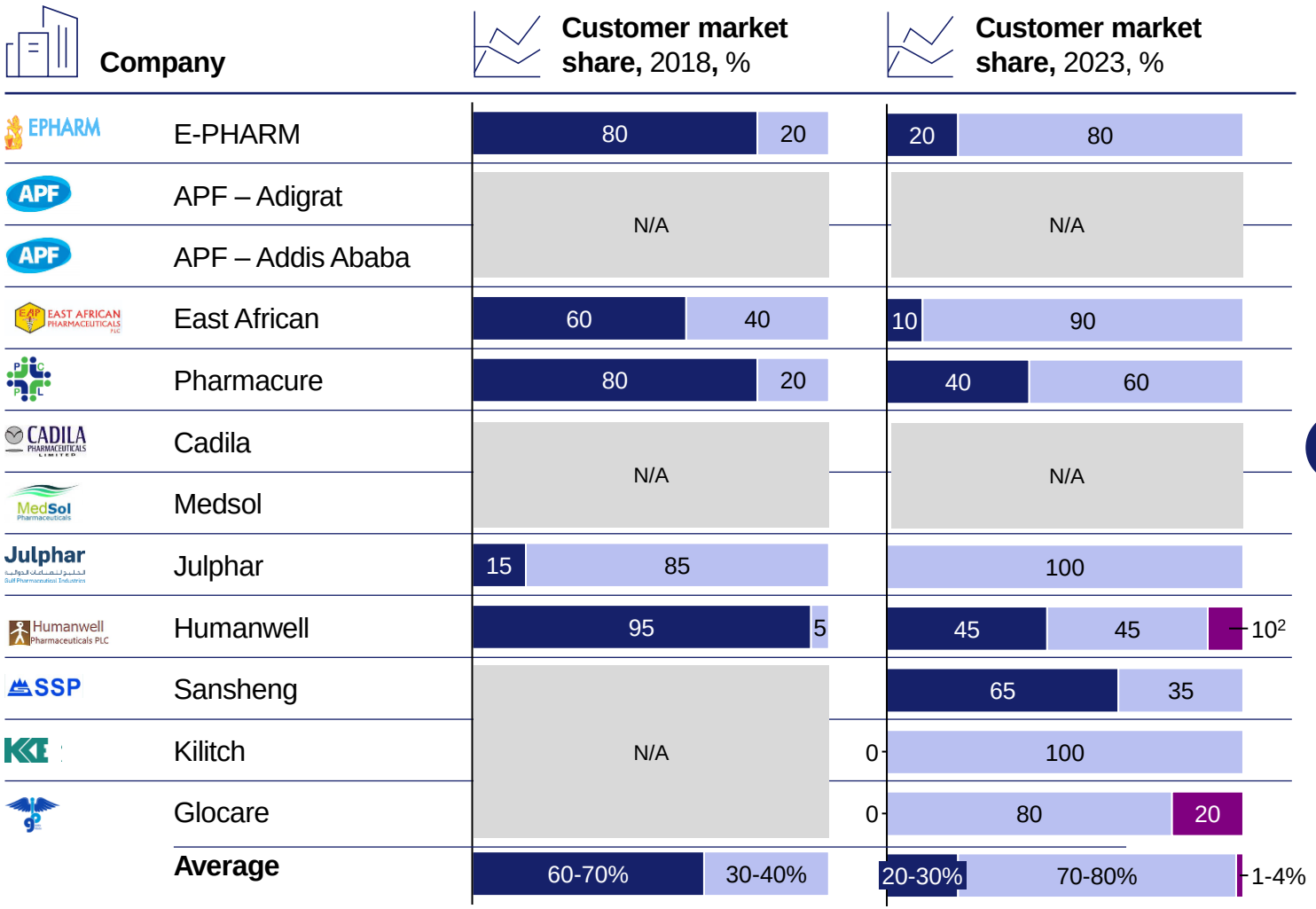
In the last five years, local manufacturers have significantly shifted their customer base from the public to the private market



60 to 20%

The share of total manufacturers' revenue from EPSS dropped from 60 to 20% in the last five years

- Due to increasing **barriers to local production** over the last 5 years, manufacturers' cost of production has increased

- Currently, **local manufacturers primarily serve the private market because the market is less competitive,** and they are able to provide products at acceptable prices (**prices in the private market are at least 10% higher** than the public market)

- EPSS has been **substituting these volumes with imports**, which have in parallel increased in the last 5 years.

1. Currently exporting to 3 West African markets, namely Mali, Burkina Faso and Niger

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Challenges affecting companies to utilize full capacity include shortage of forex, lack of local capability, and trade & regulatory challenges

Summary of main challenges and barriers of local production expressed by manufacturers

Level of concern ● High ◐ Medium ○ Low

Theme	Main Challenge	Description of challenge by manufacturers
Shortage of Forex	**Shortage in foreign currency to purchase inputs and machinery**	● "We are surviving with **less than 10% our available production capacity** due to lack of forex" "We had plans to double our production capacity and increase our product portfolio, but the lack of forex **delayed this investment** needed for import of machinery" "The current **forex allocation trend favors pharma importers rather than manufacturers**, as they have more access to forex than us"
Lack of local capacity and capability	**Lack of locally available inputs**	● "There is no API manufacturing plant in Ethiopia, so we have to **cover all our API needs through import"** **"**There is a **shortage of inputs** – spare parts, chemicals, packaging. There are essentially **no inputs we can obtain locally**"
	Lack of equipment calibration and maintenance services	◐ "Less than **20% of our calibration need is covered locally,** it is a big **bottleneck!"** **"**Calibration and maintenance is **costly** and **increases downtime** because we have to send the equipment abroad or fly experts to Ethiopia, if the equipment is big"
Trade and regulatory challenges	**Sub-optimal taxation regime**	◐ **"**There are **various tax irregularities** that the government can look into and fix"
	Customs delays	◐ **"**There are **various delays and bureaucracy in customs and logistics**" **"**We deal with **delays** and **lengthy logistics process.** The pharma sector should be prioritized through a green corridor."

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SECTION A: Overall key insights and action plan

SECTION B. Demand overview

SECTION C: Regulatory pathways overview

SECTION D: Manufacturers overview

SECTION E: General tablets/capsules business case

SECTION HF Other high-level business cases

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General product tablets and capsules manufacturing can be shown in 3 macro steps: Pre-production, Upstream and Downstream Production

Focus for Ethiopia local manufacturing detailed next

Stage	Pre-production	Upstream Production	Downstream Production		
Process	Sourcing	Intermediates & API production	Formulation[1]	Primary packaging	Secondary packaging
Description	Raw materials Packaging materials Services Infrastructure Engineering Operational supplies	Reacting Isolation and Purification Packaging	Tablets Capsules	Blisters Bottles Sachets	Folding box Carton

Local manufacturing of APIs and intermediates is very limited

Ethiopian manufacturers perform all downstream production processes

1. List not exhaustive

Source: POBOS, McKinsey pharmaceuticals practice, Expert interviews

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The downstream manufacturing process of general tablets is modular enough to manufacture various types of tablets and…

Modular production process between different products

Unique process only for tablet and not capsules

Stage	Raw material handling	Conversion	Compression	Coating	Primary packaging	Secondary packaging
Process	Receiving	Blending	Dry granulation Wet granulation Extrusion	Tablet compression/ embossing	Tablet coating	Tablet printing	Primary packaging	Secondary packaging
Description	Raw materials are received in drums, storage bags or containers. They are weighed and stored for processing	Raw materials and APIs are blended Achieving a homogenous blend of solid particles provides unique challenges compared to mixing liquids	Following particle size reduction and blending, the formulation may be granulated, which provides homogeneity of drug distribution in blend.	The compression is done either by single punch machine (stamping press) or by multi station machine (rotary press). The tablet press is a high-speed mechanical device. It 'squeezes' the ingredients into the required tablet shape with extreme precision	Using tablet coating, polishing , and printing machines, the tablet is coated and potentially printed with a serial number or tag.	Added to Blister packers, capped container, etc. Sealed and labeled	Individual packages are collated into cartons, cases, etc.

Particular unit manufacturing processes for different tablet products might look different. For example, some tablet products go through 2-3 compressions, or multi layer coating

Source: POBOS, McKinsey pharmaceuticals practice, Expert interviews

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…can be minimally adjusted to manufacture capsules, which have a similar production process

Modular production process between different products

Unique process only for capsules not tablets

Stage	Raw material handling	Conversion	Encapsulation	Primary packaging	Secondary packaging	
Process	Receiving	Blending	Dry granulation Wet granulation Extrusion	Capsule compression/ embossing	Primary packaging	Secondary packaging
Description	Raw materials are received in drums, storage bags or containers. They are weighed and stored for processing.	Raw materials and APIs are blended. Achieving a homogenous blend of solid particles provides unique challenges compared to mixing liquids	Following particle size reduction and blending, the formulation may be granulated, which provides homogeneity of drug distribution in blend.	Capsules are filled, printed and sorted	Added to Blister packers, capped, sealed and labeled	Individual packages are collated into cartons, cases, etc.

Particular unit manufacturing processes for different tablet products might look different. For example, some tablet products go through 2-3 compressions, or multi layer coating

Source: POBOS, McKinsey pharmaceuticals practice, Expert interviews

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There are two main manufacturing approaches that could be taken

PRELIMINARY

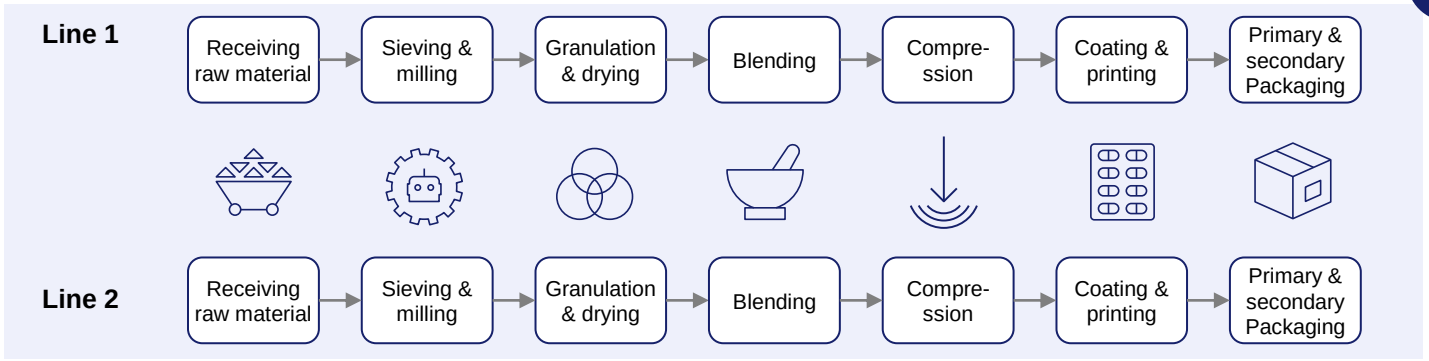
More suitable for large individual product volumes & specialization

More suitable for lower individual product volumes and various products

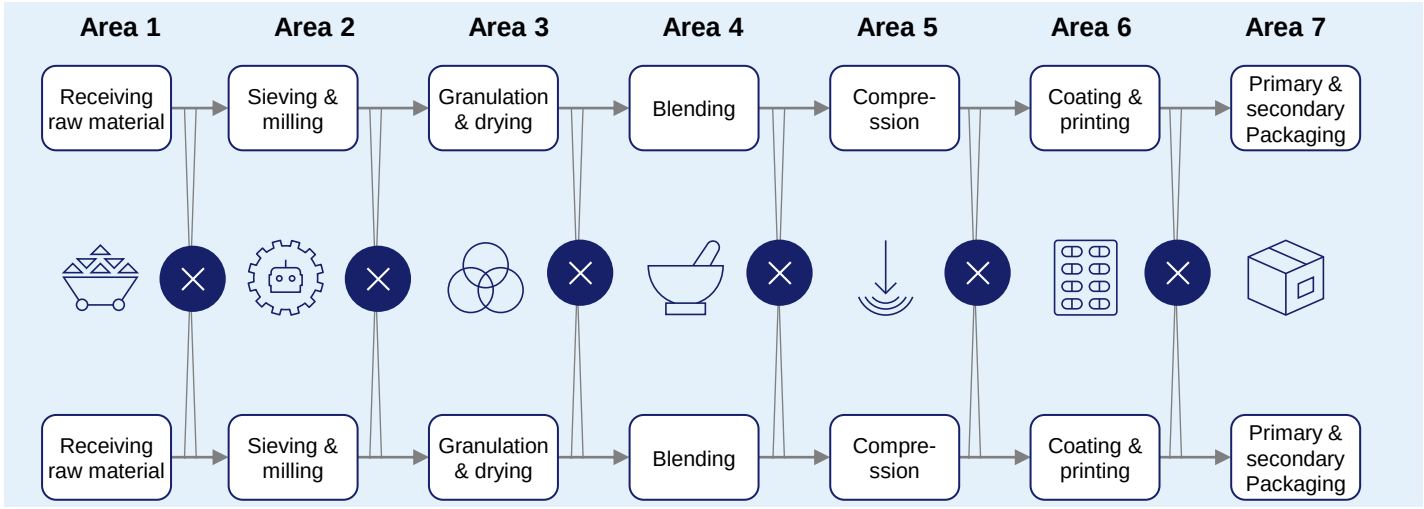
Mfg. approach

High level tablet manufacturing process

Parallel



Non- parallel / matrix



Key insights

- In **parallel manufacturing**, **product is manufactured continuously** with one-to-one process mapping and is **more suitable for large volume production**
- In **non-parallel or matrix type, production steps are organized into cohesive suites/areas** with many-to-many mapping and **enhances production flexibility and allows non-continuous production**
- Large scale manufacturers **produce multiple products on number of manufacturing lines (incl. both approaches)**
- Local manufacturers **should have more parallel production approaches to maximize scale and efficiency**

1. Process Analytical Technology

Source: Expert interviews

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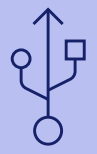
Generally, there are some key operational considerations to have in mind when developing a tablets/capsules business case

Product flexibility

Most types of tablets and capsules (with some exceptions, e.g., high intensity drugs and beta lactams) can be produced on the same production line with **8 – 16 hrs.** transition time between different products, for cleaning and modification

Operational excellence

It takes usually **3 – 4 years** to get to a level of strong performance, and potentially longer to reach top level performance



Manufacturing process

Production/conversion cost varies substantially for different products, despite products having similar process. This is due to different operations for drugs. E.g., some tablets go through 2-3 compressions (bilateral tablets)

Product portfolio complexity

Focus of production on a limited number of products **leads to higher efficiency**, which is particularly important for low volume production. Despite this, **50 – 70** is the typical number of products produced by global leaders' plants (>4b tablets per year)

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Scale is an important determinant of pharmaceutical production efficiency

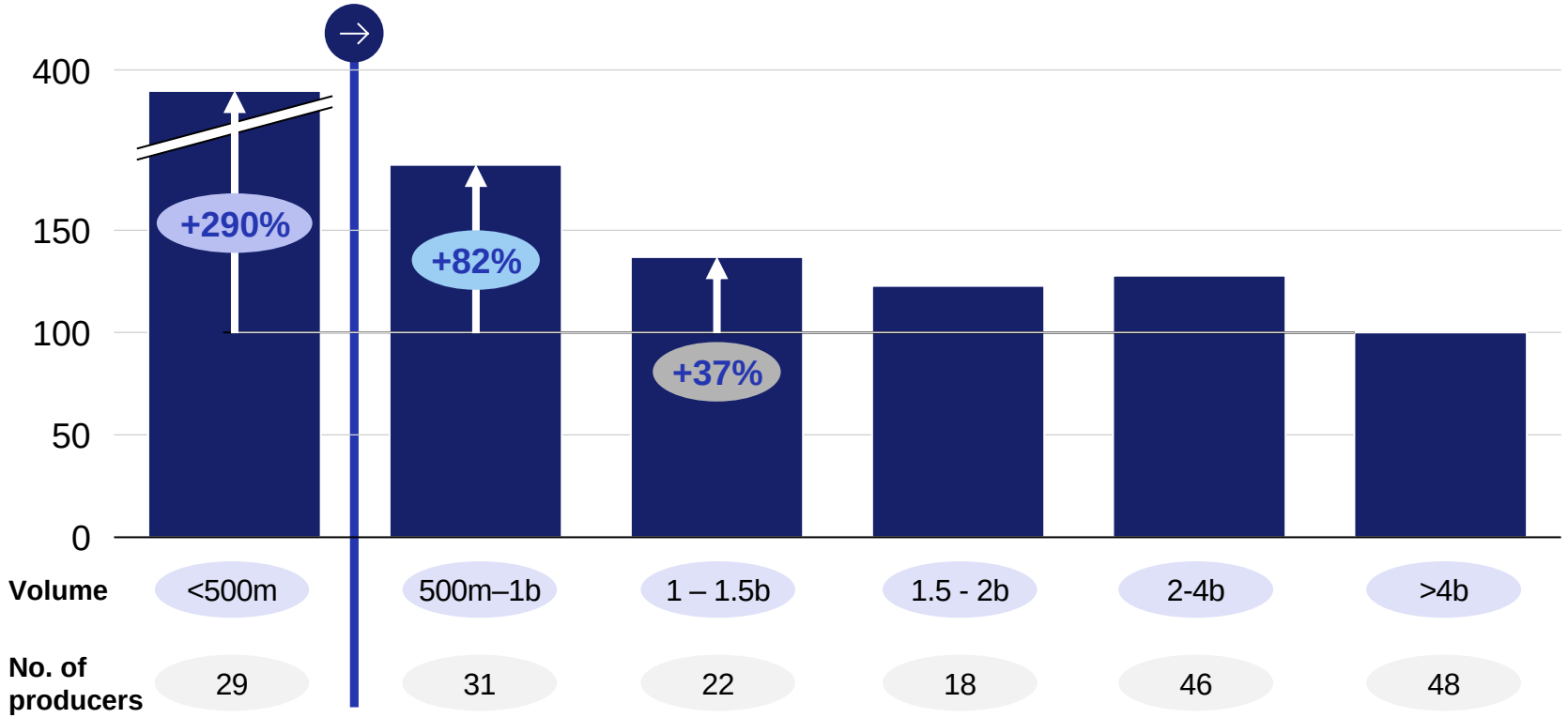
xx Top quartile comparison for 500m vs >4b

xx Top quartile comparison for 500m – 1b vs >4b

xx Top quartile comparison for 1 – 1.5b vs >4b

Optimal volume for competitiveness

Normalized conversion cost of top quartile performers PU[1,2], Top quartile cost at scale of >4b = 100



Key insights

- It is **difficult to be competitive at scales below 500m per year**, due to relatively very high conversion costs
- **Scale is important to keep conversion costs low**
- However, there is a **significant variance in conversion costs among manufacturers** producing at the same scale

1. Based on McKinsey global pharmaceutical benchmark of ~200 pharmaceutical manufacturers around the world
2. Normalized median cost per unit (PU) is normalized against the top performers which scale of above 4b = 100. All the other medians and quartiles are relative to top performers

Source: McKinsey benchmarking tool (POBOS)

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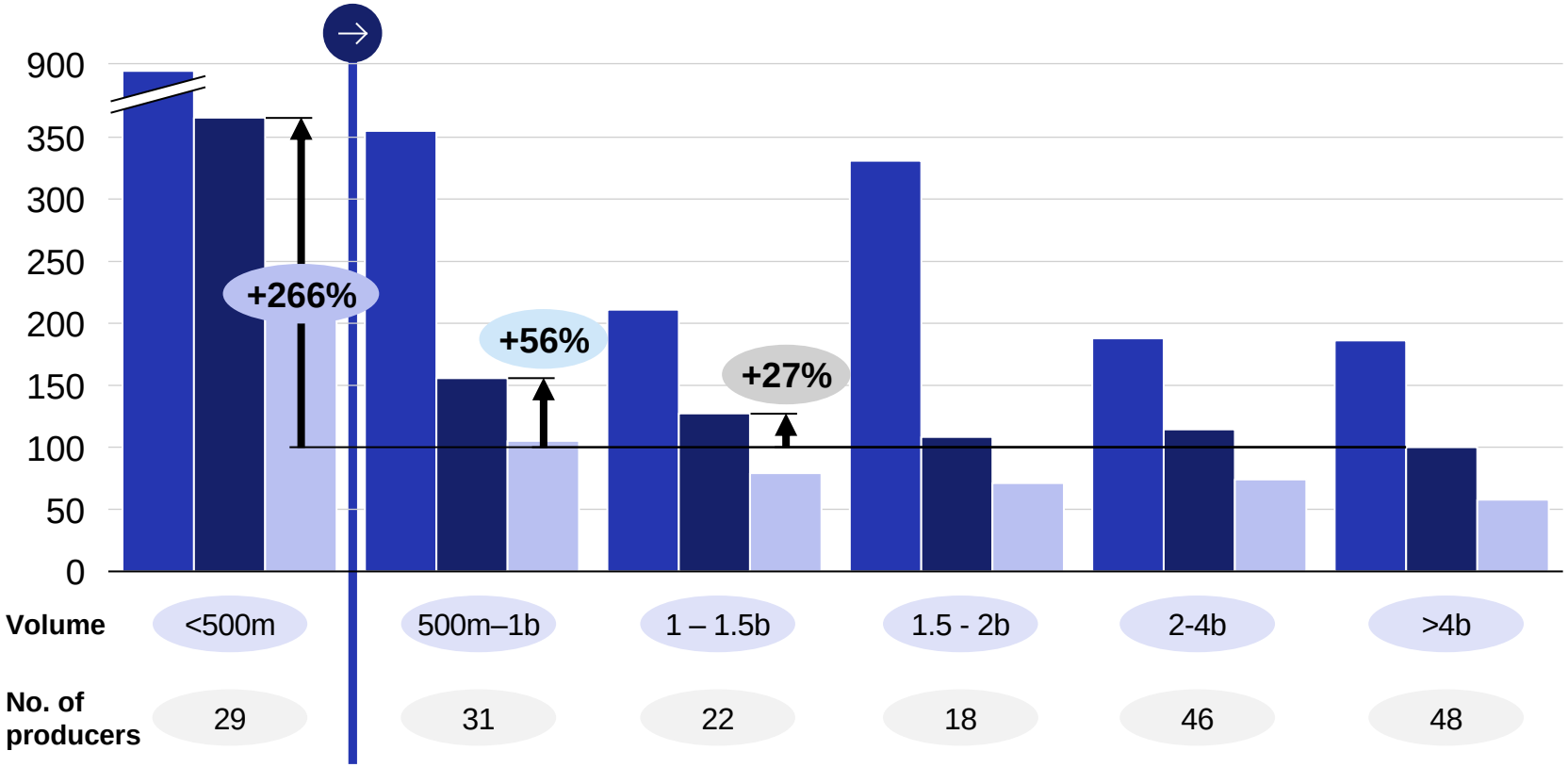
While there are significant differences in performance of similar volumes, scale is an important determinant for production efficiency

Bottom quartile cost PU | Median cost PU | Top quartile cost PU

xx Median comparison for 500m vs >4b
xx Median comparison for 500m – 1b vs >4b
xx Median comparison for 1 – 1.5b vs >4b

Minimum volume required for competitiveness

Normalized conversion cost PU[1,2], median cost at output of >4b = 100



Key insights

- There is **significant variance conversion costs among manufacturers** producing at different scales. **Costs can also look different among producers at similar scale**
- Typically, **scale is critical to keep conversion costs low** and best-in-class players produce significantly large volumes
- It is **difficult to be competitive at scales below 500m per year**, due to relatively high conversion costs

1. Based on McKinsey global pharmaceutical benchmark of ~200 pharmaceutical manufacturers around the world
2. Normalized median cost per unit (PU) is normalized against the top performers which scale of above 4b = 100. All the other medians and quartiles are relative to top performers

Source: McKinsey benchmarking tool (POBOS)

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Local demand in Ethiopia is likely insufficient to enable the achievement of high-enough scale, highlighting the potential need for exports

HIGH-LEVEL NUMBERS

x EPSS top tablets/capsules

Top 10 tablets/capsules procured, 2022

Ethiopia

Drug name	Description	Number of tablets, Bn	Sales value, 2022, $M
1 DLT[1]	Anti-retroviral medicine	0.17	33.6
2 ELT[2]	Anti-retroviral medicine	0.02	4.4
3 atazanavir + ritonavir	Anti-retroviral medicine	0.01	4.1
4 artemether + lumefantrine	Antimalarial medicine	0.12	3.3
5 HRZE[3]	Antituberculosis medicine	0.05	3.1
6 doxycycline	Antibiotic medicine	0.07	2.1
7 ferrous salt + folic acid	Antianemia medicine	0.26	1.9
8 metronidazole	Antibiotic medicine	0.21	1.8
9 Co-trimoxazole[4]	Antibiotic medicine	0.09	1.6
10 mebendazole	Intestinal Anthelminthics	0.04	1.4
	EPSS other	1.20	92.1
	EPSS total	2.25	149.3
	Private market total[5]	3-5	160-200
	Total	5-7	310-350

Africa Total for tablets/capsules[6]

140 - 150bn

Volume, 2022 tablets/capsules

8 - 12bn

Value, 2022 USD

While the public market is the largest value market in Ethiopia, the private market is also growing and has a significant share of the overall pharma market (~45%) and most of the volumes (~55%)

1. Contains dolutegravir, lamivudine and tenofovir
2. Contains efavirenz, lamivudine, and tenofovir
3. contains ethambutol, isoniazid, pyrazinamide and rifampicin
4. Sulfamethoxazole + trimethoprim
5. Is based on an estimate from the value of the private market
6. African numbers are estimates based on logistics data

Source: EPSS, UN Comtrade

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The overall product cost structure of tablet & capsule manufacturing has multiple dimensions with varying sensitivity

Assumed at optimum scale for best-in-class manufacturers

Low · High · X Detailed next

Cost categories[1]	Subcategories	Sensitivity to volume	Description	Best in class share of cost	Ethiopia's relative competitive local disadvantages against best in class
1 **Raw material[2]**	**API[4]**		Active therapeutic substances, which carry the highest share of the cost structure	**40 - 60%**	⊕ Local cost disadvantages may be present due to small scale & lack of upstream integration
	Excipient		Inactive substances to ensure stability of the drug	**10 – 15%**	⊕ Cost disadvantages may be present due to small scale & lack of upstream integration
	Packaging		Packaging material that depend on the type of drug and chemical sensitivity	**7 – 15%**	⊕ Cost disadvantages may be present due to small scale & lack of upstream integration
2 **Conversion**	**Utility**		Power, water and other utility costs	**3 – 7%**	⊖ While local utility costs are lower vs. India or China, this is offset by relatively frequent power outages
	Labor		Skilled and unskilled labor for production	**10 – 15%**	⊖ Labor costs are substantially lower locally but to some extent, offset by low productivity
	Machinery		Machinery costs include the depreciation cost for all machinery as well as the costs of maintaining it	**5 – 10%**	⊕ Local Machinery costs are higher due to lower volume produced locally & distance from their manufacturing place (incl. spares)
	Other costs[3]		Facilities, regulation, other capex, and miscellaneous costs	**5 - 10%**	⊕ Might be lower for scale local producers, but is estimated to be equal at realistic scale

1. This cost structure is excluding margin 2. Raw material cost is only looking at the FOB cost and the share may change per drug 3. Most other costs are related to conversion costs such as consumables, spare parts, quality and compliance 4. This is for high-cost API drugs. However, API costs and share of the of the manufacturing cost can significantly change can be 50% lower in share of manufacturing cost for low-cost API drugs

Source: Expert interviews

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1 Various factors affect the price of raw materials, which can also look different between manufacturers producing similar products

NON-EXHAUSTIVE

Factors affecting raw material costs per unit

Dimensions	Description
Market & supply	**Supply and demand play a significant role in prices** of raw materials. APIs with limited number of producers have high control on prices. **Some formulated drugs like TLD and TLE are produced by backward integrated producers who also produce the APIs**, making it difficult to compete with. Excipients and packaging can also have different prices based on supply for different drugs
Production complexity	**Complexity and efficiency of manufacturing processes for raw materials can influence costs** (e.g., extensive R&D and patenting costs). Customization can also add to costs
Location	**Proximity** to raw materials producers **can significantly reduce transportation costs and streamline the supply chain.** This can also **impact production planning by facilitating more efficient just-in-time production**, minimizing the need for extensive warehousing
Procurement strategies	**Larger volume procurements** may create benefits from economies of scale, **allowing for negotiation of better prices with suppliers**. Smaller procurements may create higher per-unit costs
Regulatory compliance	**Stringent regulations in some API & excipient production can contribute to increased costs**. Compliance with regulatory standards often involves additional testing, documentation, and quality control measures

Source: Expert interviews

Key takeaways

- Raw materials costs can be significantly **different between different drugs as well as different manufacturers**
- Manufacturers that have **upstream integration can have lower raw material costs** and are able to be very competitive in their formulated products
- **More complex products that have number of APIs & excipients** (e.g., TLD & TLE) **can also have higher costs than generic and commoditized products** (e.g., Paracetamol)
- Formulators can also **leverage different negotiating incentives such as large volume purchases** as well as **long-term relationships**

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2 There are also significant differences in conversion costs between different drugs and plants due to a range of factors

NON-EXHAUSTIVE

Factors affecting conversion cost per unit

Dimensions	Description
Manufacturing technology	Choice of **manufacturing technology and facilities can affect conversion costs**. **Different techniques result in different costs per tablet**
Production complexity	**Complexity of the drug formulation** can significantly impact conversion costs **due to additional & complex processes, advanced equipment need, specialized facilities** etc. (e.g., some tablet undergo 2-3 compressions, or multi layer coating)
Asset productivity & utilization	Effective asset productivity & utilization is vital for conversion cost (e.g., minimizing idle time). Achieving efficiency in **production transitions & planning** is challenging but crucial, **necessitating the alignment of capacity with demand**
Labor productivity	**Both production and non-production labor productivity can significantly impact costs**. **Higher capability & productivity can lower costs**, which can be achieved through continuous training & upskilling
Scale	**Large-scale manufacturing benefits from economies of scale**, leading to lower costs per unit. Products produced at scale have lower conversion cost compared to low volume products
Regulatory compliance	Compliance requirements can impact conversion costs such that **drugs subject to more stringent regulatory standards or those requiring specialized facilities** to meet GMP guidelines may incur higher costs

Source: Expert interviews

Key takeaways

- **Conversion costs can very significantly** between different drugs and plants/manufacturers
- It is **difficult to get to top-quartile of cost per unit** as it requires high efficiency & specialization
- Differences in conversation costs per unit can also be seen between programme and non-programme drugs:
  - **Programme drugs can typically have higher conversion costs** due to higher regulatory requirements and complex production requirements
  - **Non-programme and generic drugs may have relatively less conversion costs due to** high scale and less complex manufacturing process

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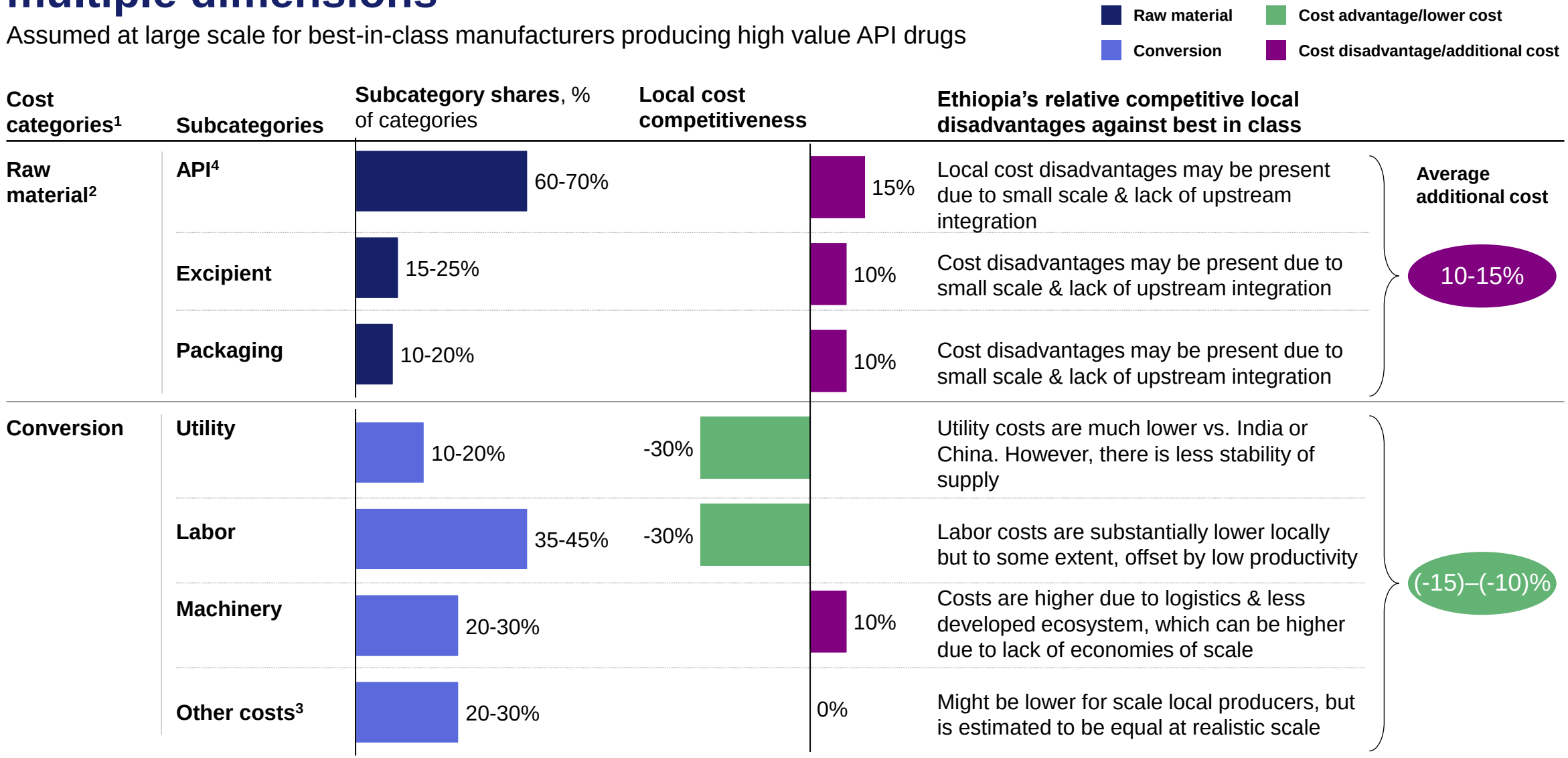
The overall product cost structure of tablet & capsule manufacturing has multiple dimensions

Assumed at large scale for best-in-class manufacturers producing high value API drugs



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Source: Expert interviews

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Local manufacturing of programme drugs for local demand could become competitive in medium to long term with limited procurement incentives

Conversion
Raw material
Import and duties cost
Landed cost of drugs

xx Additional cost to local 500m scale from imported
xx Additional cost to local 4b scale from imported

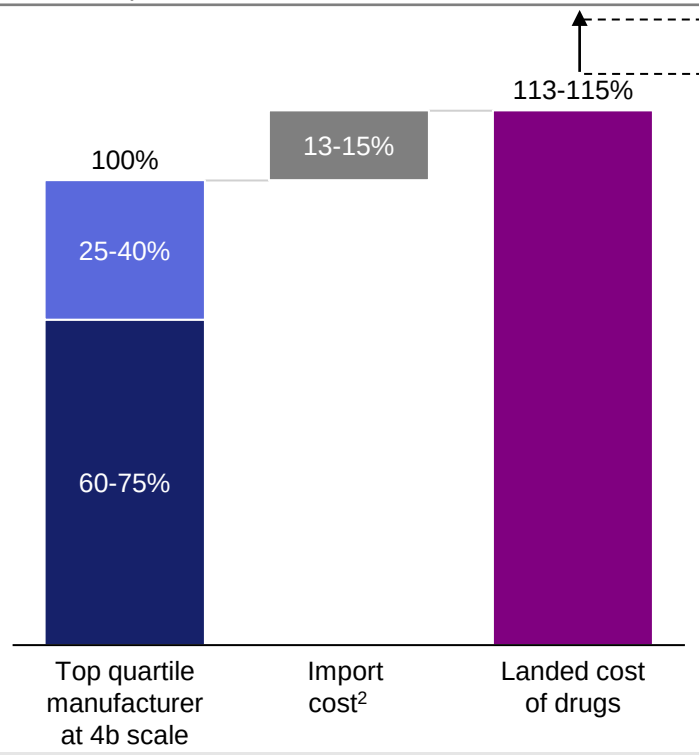
Local scenarios detailed next

Main pre-conditions

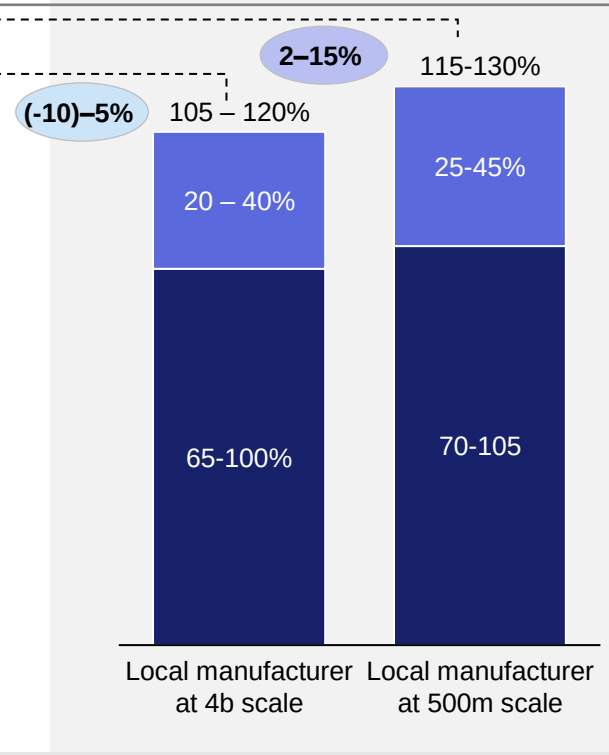
- Local manufacturers **produce at top quartile operational efficiency,** which is difficult to achieve and takes significant amount of time (at least 3-4yrs.)
- Manufacturers achieve **large scale production** volumes, **by obtaining access to international markets** through the adoption of more export friendly FX rules and other market access initiatives
- **Local production conditions such as; utility stability and labor productivity** are high and are competitive with best-in-class producers

Cost of importing drugs from top quartile

% of cost per tablet



Relative cost of production in Ethiopia[1], % of cost per tablet



Local manufacturers in median performance, can have additional 5-15 p.p. cost of manufacturing, which makes them less competitive (esp. at lower scales)

1. Relative cost of production of local manufacturer producing programme, compared to best-in-class manufacturer
2. Import cost is airfreight, transport insurance and any other logistics related costs. There are also some duties that apply such as contribution tax accounting up to 5%. This is based on an average for imported products from best-in-class (India)

Source: Expert interviews, McKinsey benchmarking tool (POBOS), Prices and availability of locally produced and imported medicines in Ethiopia (WHO)

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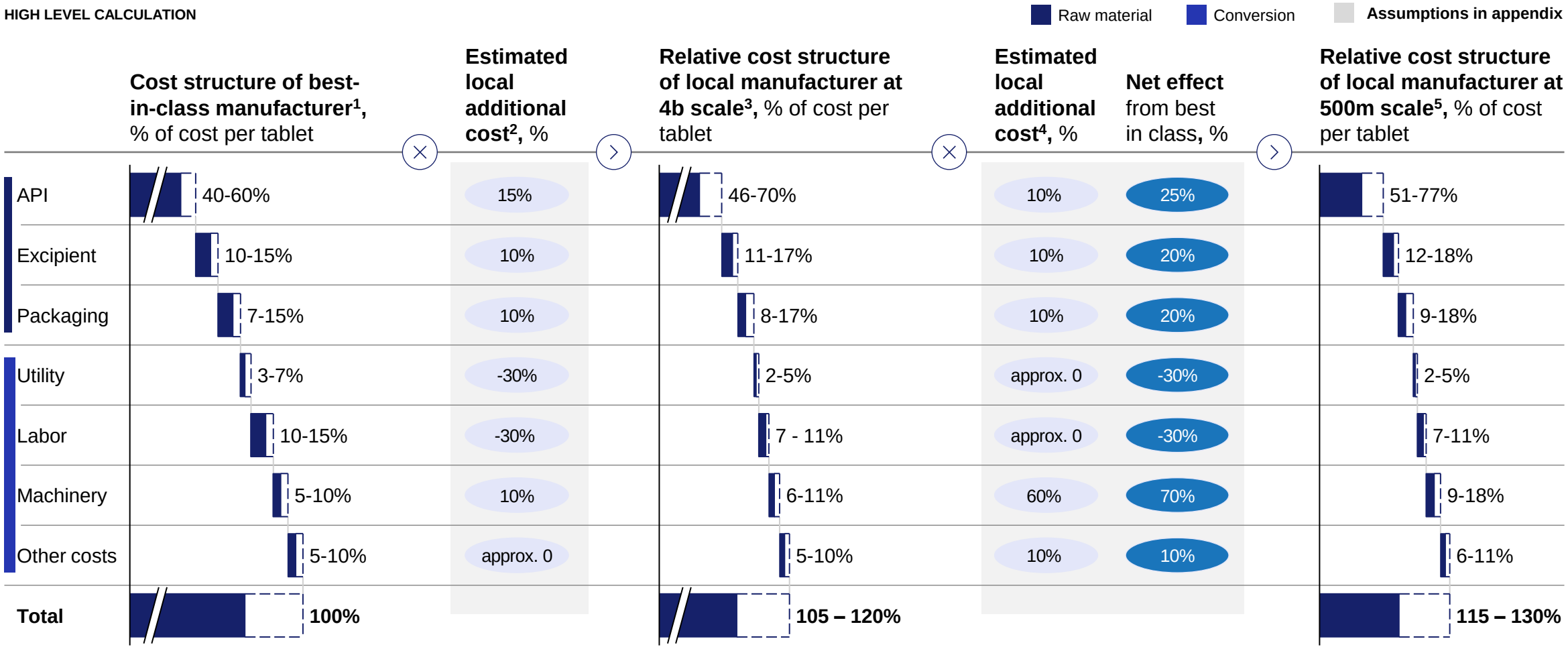
Depending on scale, local manufacturing of drugs that have high API costs may incur costs 5– 30% higher than the best-in-class producers

Average manufacturing cost comparison of Ethiopian manufacturing vs best-in-class

HIGH LEVEL CALCULATION



This cost structure excludes margins. However, margins typically are expected to be higher in Ethiopia due to relatively lower volume

1. Are large scale producers (>4b per year) and have upwards integration, 2. Additional percentage of costs that would be added due to Ethiopian local context (e.g., logistics & monopolized API prices) 3. Best-case-scenario for local manufacturing at similar scale and top quartile efficiency as best in class manufacturers (>4b tablets) 4. Additional cost effects due to low scale production (e.g., higher conversion cost) 5. Realistic cost estimate for a local scenario at 500m scale top quartile efficiency

Source: Expert interviews, McKinsey benchmarking tool (POBOS), World Bank Policy Research Working Paper 8980, 2019, Cost of Power Outages for Manufacturing Firms in Ethiopia, A simulation study of pharmaceutical industry in low-income Africa, www.xeneta.com

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For more commoditized, low API value drugs, the business case for local manufacturing for local demand is stronger

Conversion
Raw material
Import and duties cost
Imported cost

xx Additional cost to local 500m scale from imported
xx Additional cost to local 4b scale from imported

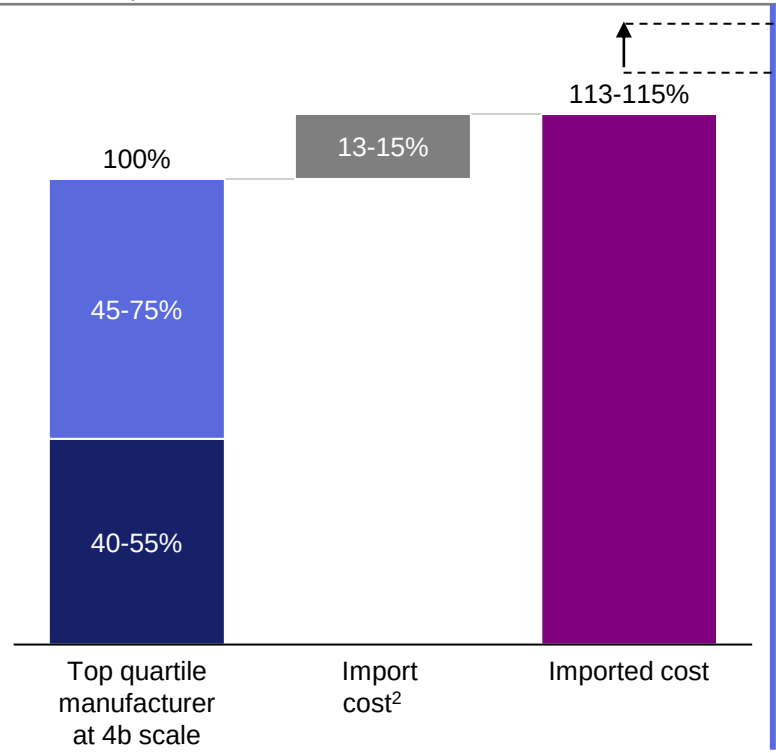
Local scenarios detailed next

Main pre-conditions

- Local manufacturers **produce at top quartile operational efficiency,** which is difficult to achieve and takes significant amount of time (at least 3-4yrs.)
- Manufacturers achieve **large scale production** volumes, **by obtaining access to international markets** through the adoption of more export friendly FX rules and other market access initiatives
- **Local production conditions such as; utility stability and labor productivity** are high and are competitive with best-in-class producers

Cost of importing drugs from top quartile

% of cost per tablet



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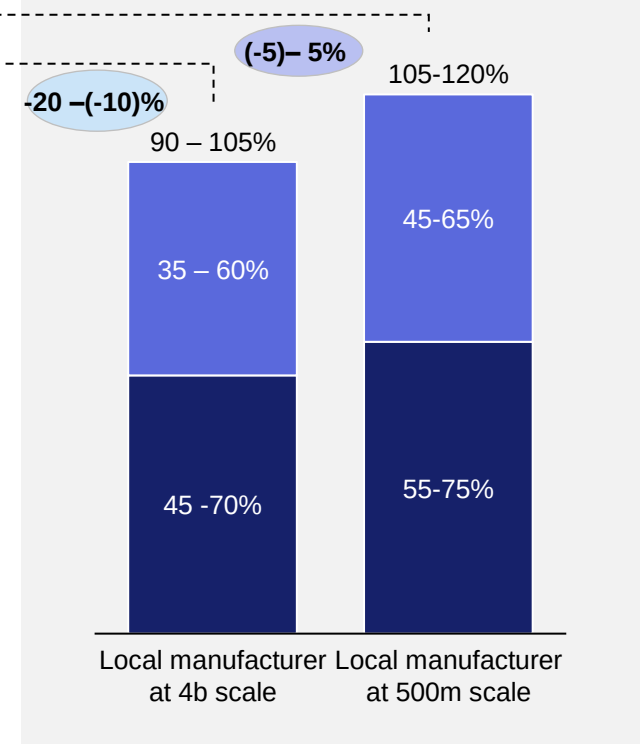

Local manufacturers in median performance, can have additional 5-15 p.p. cost of manufacturing, which makes them less competitive (esp. at lower scales)

1. Relative cost of production of local manufacturer producing programme, compared to best-in-class manufacturer
2. Import cost is airfreight, transport insurance and any other logistics related costs. This is based on an average for imported products from best-in-class (India)
3. Programme drugs are also exempt from most types of the taxes and customs fees like VAT. However, there are some that apply such as contribution tax and other taxes accounting upto 5%

Source: Expert interviews, McKinsey benchmarking tool (POBOS), Prices and availability of locally produced and imported medicines in Ethiopia (WHO)

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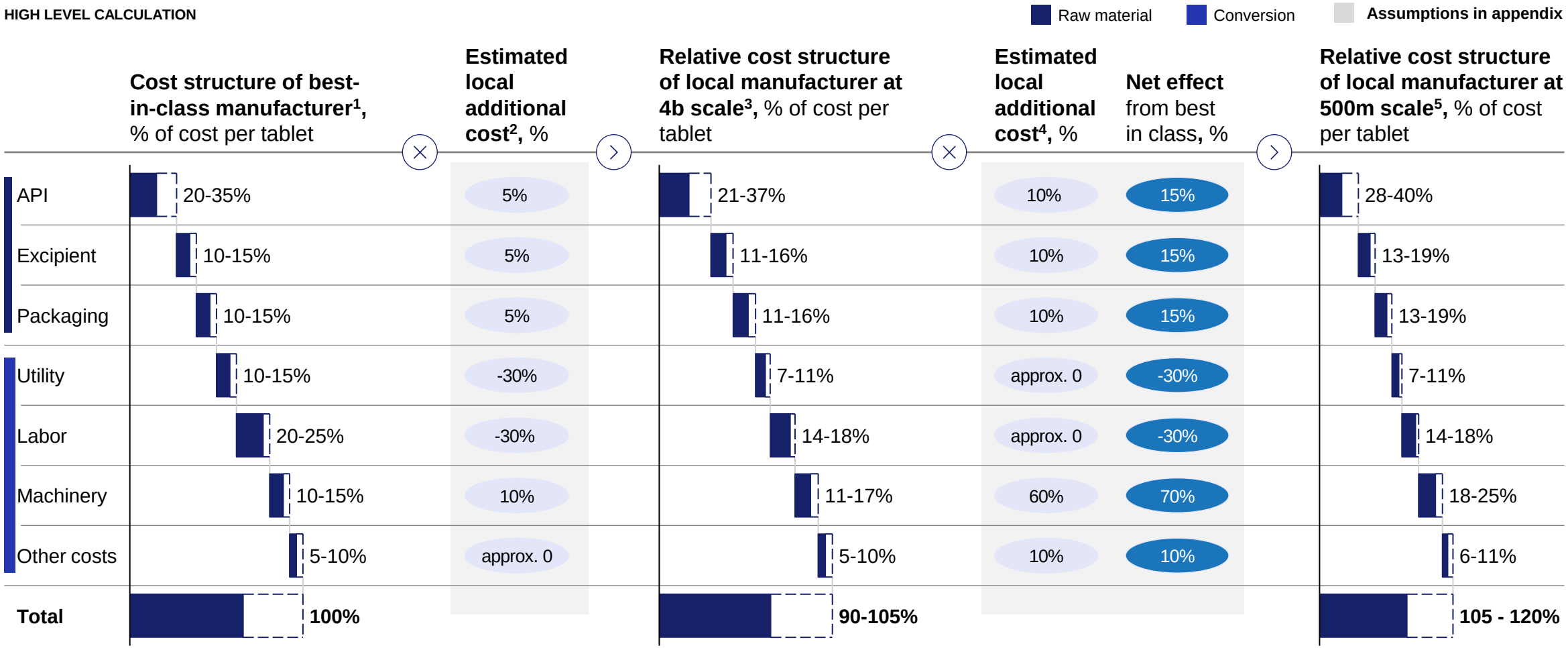
Depending on scale, local manufacturing of low API drugs may incur costs -10% up to 20% than the best-in-class producers

Average manufacturing cost comparison of Ethiopian manufacturing vs best-in-class

HIGH LEVEL CALCULATION



This cost structure excludes margins. However, margins typically are expected to be higher in Ethiopia due to relatively lower volume

1. Are large scale producers (>4b per year) and have upwards integration. Drugs with low API costs have higher share of conversion PU but actual conversion costs may not be higher than drugs with high API 2. Additional percentage of costs that would be added due to Ethiopian local context (e.g., logistics) 3. Best-case-scenario for local manufacturing at similar scale and top quartile efficiency as best in class manufacturers (>4b tablets) 4. Additional cost effects due to low scale production (e.g., higher conversion cost) 5. Realistic cost estimate for a local scenario at 500m scale top quartile efficiency

Source: Expert interviews, McKinsey benchmarking tool (POBOS), World Bank Policy Research Working Paper 8980, 2019, Cost of Power Outages for Manufacturing Firms in Ethiopia, A simulation study of pharmaceutical industry in low-income Africa, www.xeneta.com

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In the long-term if raw material sourcing is further improved, Ethiopia could become a high potential exporter

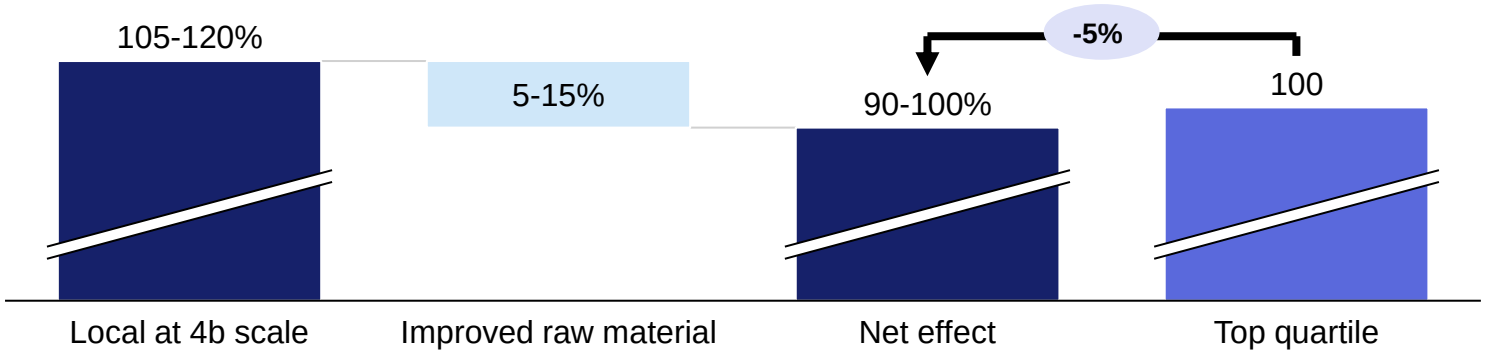
Top quartile performance achieved for local manufacturers at scale

xx Average relative cost difference

- Local manufacturers have additional costs relative to best-in-class **due to the logistics cost of importation of raw materials and lack of vertical integration**
- **Raw material disadvantages significantly affect drugs that have a high cost of API**, which are typically program drugs like TLD and TLE
- **If local manufacturers can procure raw materials locally, they can significantly be competitive** with best-in-class players
- They can also explore the potential for local manufacturing of raw materials in the long term

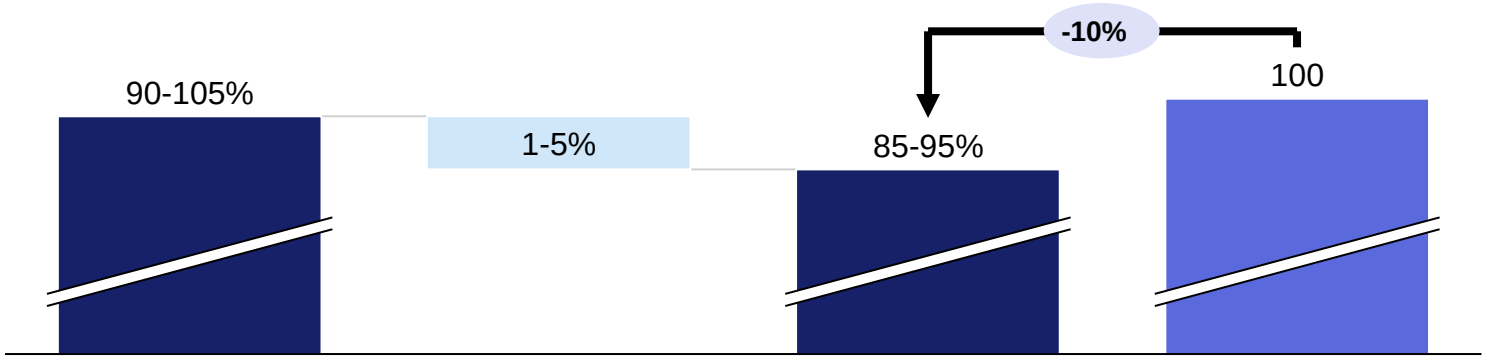
High API value drugs cost comparison relative to best in class,

% of cost per tablet



Low API value drugs cost comparison relative to best in class,

% of cost per tablet



Local manufacturers in median performance, can have additional 5-15 p.p. cost of manufacturing, which makes them less competitive (esp. at lower scales)

Source: Expert interviews, www.naruc.org, https://www.globalpetrolprices.com/India/electricity_prices/

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The success of the pharma industry in India, China and Bangladesh can be attributed to robust backing by government

NON-EXHAUSTIVE

Category		Examples
Supply of subsidies		• **Government subsidies to MSME & large pharma manufacturers**, under the PLI[3] scheme to incentivize local manufacturing of **53 KSMs[2], Drug Intermediates and APIs**. This also grew to **incentivizing local manufacturing of high value drugs** in PLI 2.0 • **Export focused industry development provided** offered grant to develop vaccine production
		• **Raw material import tax incentives, low custom duties, and 5 to 7 yrs. tax holiday**, by the government to incentivize investments • **Co-investment of government and control of the price of all raw materials** in use by the sector, ranging from APIs to excipients and packaging material
		• **R&D subsidies for pharmaceutical sector** by the government
Improvement of structural operational conditions and regulation		• **Encouragement of the entrance of multinationals** into the market by **eliminating licensing requirement**, and the authorization of 100% of inward FDI • Provision of **low interest government loans to manufacturers to upgrade technology and infrastructure** • **Establishment of the National Institute of Pharmaceutical Education and Research (NIPER**) • **Intellectual property law reform[1]**, allowing only the patenting of manufacturing processes and enabling reverse engineering of drugs at low cost. However, this IP law was amended to be compliant with World Trade Org. (WTO) • **Pricing controls** by the government which ensured drug accessibility, promoted generic drug production health competition, prevented exploitative pricing
		• **Creation of the Active Pharmaceutical Ingredients (API) Industrial Park** by the government facilitated local raw material industry • **Control and even ban of foreign importation of drugs** when there is enough local supply (>3 manufacturers)
		• **Strengthening of domestic, state-led industrial development**, with an important role for state-owned enterprises • **Developing favorable conditions for multinationals through market reforms** which opened China to foreign investment

1. Enactment of the Patents Act in 1970 and revised in 2005. Now all member states are required to provide product patents 2. Key starting materials 3. Production Linked Investment

Source: "India Pharma 2020 Propelling access and acceptance, realising true potential" by McKinsey & Company; India Brand Equity Foundation; Invest India; European Pharmaceutical Review; World's Top Exports; Institute for Health Metrics and Evaluation; PharmaBoardroom; World's Top Exports: IQVIA Analytics Link; World Bank World Development Indicators; strapi.eacgermany.org, press search, Expert interviews

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SECTION A: Overall key insights and action plan

SECTION B. Demand overview

SECTION C: Regulatory pathways overview

SECTION D: Manufacturers overview

SECTION E: General tablets/capsules business case

SECTION HF Other high-level business cases

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RDTs present a viable business case for local manufacturing to address local and export markets

Operational considerations

While **RDTs share similar production** processes**, unit operations** for different RDTs **can be different**

Large-scale production is important for RDTs to keep fixed conversion costs low, with large global manufacturers producing well over 100m RDTs annually

They can be used for multiple diseases, but **are mainly used for Malaria and HIV in Africa** (>80% of African RDT demand)

Local context

While raw materials account for the majority of costs, **labor, and utilities account for up to 30% of production cost**, for which **Ethiopia has cost advantages of up to ~30%** vs global leaders

The local market in 2021 was 15 – 17m USD (15.5m units of RDTs), representing <1% of the global market)

There are currently two RDT producers locally with the largest being a global leader in malaria, producing with WHO-PQ approval and exporting 100% of its production

Market dynamics

The COVID pandemic highlighted the relevance of RDTs in emergency response, prompting donor interest in localizing efforts and advocating for diversified testing approaches

The RDT market is highly concentrated, with large global leaders, leading with low prices and margins. But donors are interested in de-concentrating production

Donors are the biggest buyers of RDTs (e.g., procured >90% of global malaria RDTs in 2020) and **are showing interest to by locally** (e.g., PEPFAR has committed to buy 15m RDTs locally in the next 5 years)

HIV has testing algorithms (sequence of RDTs used) **related to types of tests,** and RDTs demand is related to each country's testing rule

IP and/or brands highly affect prices and perceived quality of the products substantially in RDTs market

Quality approval (e.g., WHO-PQ) is crucial for RDTs since >80% of demand is from donors, and approval processes are quicker, through an special purpose ERP

Key insights

- **Ethiopia can become competitive in RDT manufacturing, but local demand is not enough** to achieve scale, highlighting the need for exports
- **Now is likely the ideal time to start RDT manufacturing at scale locally** due to expressed donor interest in localization
- Given the importance of IP and brand, **it would be critical to attract large international manufacturers esp. for HIV**
  - **Future guarantee commitment can be used** to stimulate investments and attract these large players
- To empower local manufacturing, **EPSS can start procuring malaria RDTs from the local manufacturer** already manufacturing with WHO-PQ standards

Source: EPSS, Unitaid malaria diagnostics, 2022, expert interviews, data bridge market research, https://www.state.gov/pepfar-sets-bold-manufacturing-targets-for-africa/

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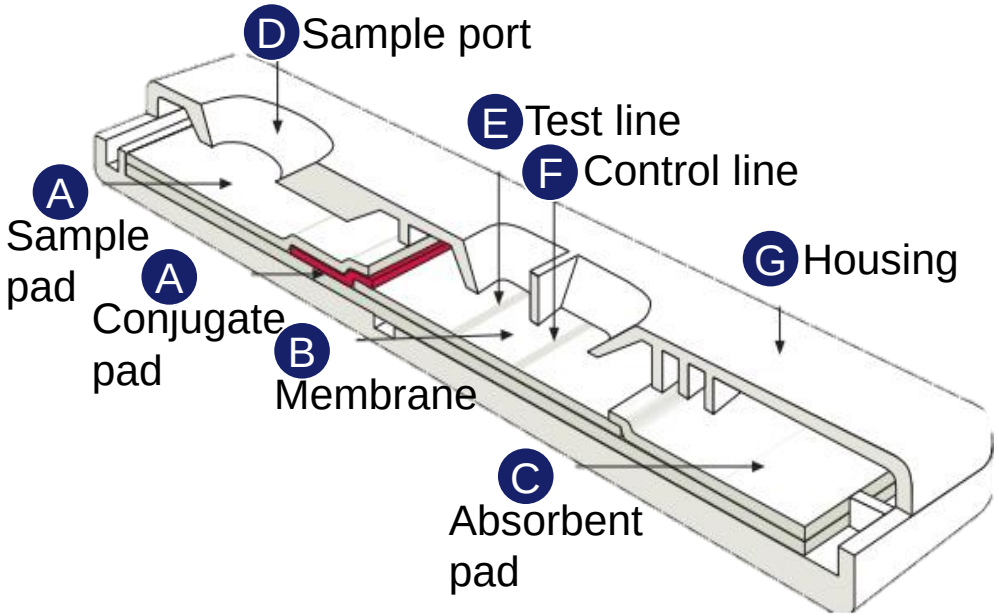
RDTs are designed to provide quick and on-the-spot results, typically within minutes, and generally a relatively simple production

Many components of typical RDTs are low-tech: Example of typical components of malaria and HIV RDTs[1]



- **A Sample & conjugate pad:** detector reagent conjugated to colored particles to capture desired analyte and released upon liquid flow
- **B Membrane:** hydrophobic membrane made of nitrocellulose to allow sample flow
- **C Absorbent pad with desiccant:** maintains flow rate of liquid through capillary action
- **D Sample port**: collects blood sample and drops of buffer
- **E Test line**: immobilized biomolecule to capture desired analyte bound to conjugated detector
- **F Control line:** species-specific anti-immunoglobulin against detector reagent
- **G Housing & backing:** inert support for membrane

1. Additional accessories include alochol wipes, lancet, capillary tube, bandages and buffer solution

Source: Expert interviews (former production managers and product managers at major manufacturers); The Global Fund Pooled Procurement Mechanism Reference Pricing – RDTs, Q2 2023 ; Alere Determination Investment Community Meeting

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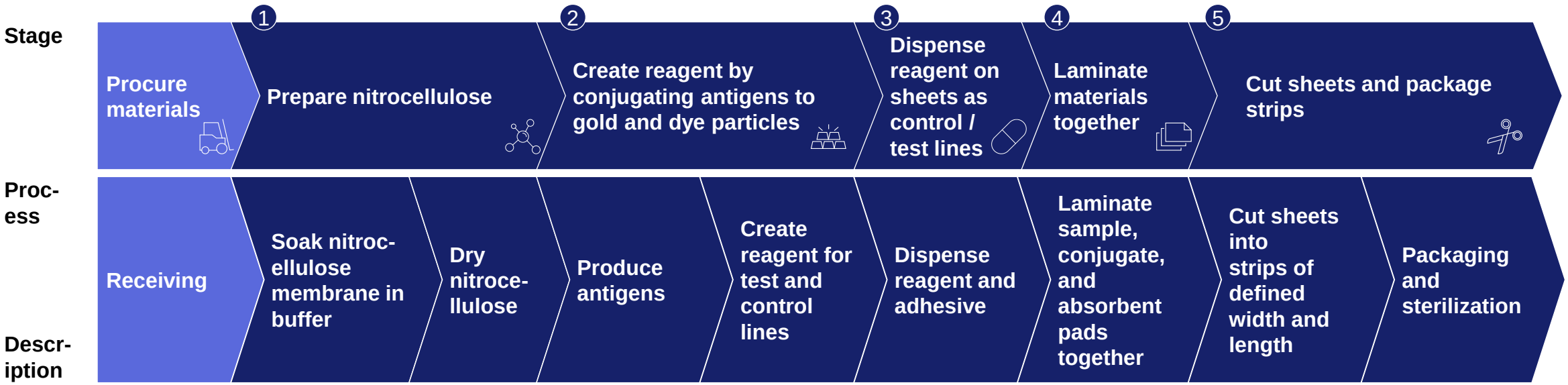
General RDTs manufacturing process can be shown in 5 macro steps



Unit operations for different RDT technologies can be different and that may impact production complexities as well as the cost of manufacturing

Source: Expert interviews (former production managers and product managers at major manufacturers)

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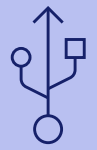
Generally, there are some key operational considerations to have in mind when developing a RDTs business case



Manufacturing process

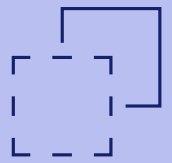
The RDT **manufacturing process is not highly complex** in comparison to other pharma manufacturing and can be done with less lead time for preparation as well as testing

Product flexibility

Multiple types of RDTs can be produced on the same production line, but costs for different RDTs can also be different due to unit operation differences (e.g., specimen volume, numbers of buffer drops, reading time)

Quality

Quality and regulatory approvals are important for RDTs, but performance differences can be present due type of technology, process of manufacturing, number of components etc.



Product variety

While there are similarities between their production process and main components, **RDTs can differ from one to another** based on types of disease and approach of diagnostics

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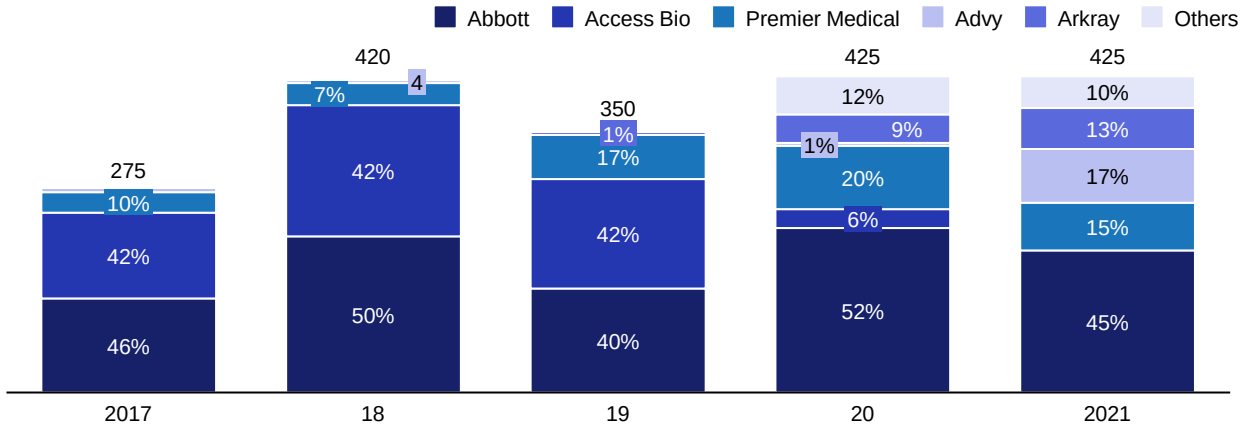
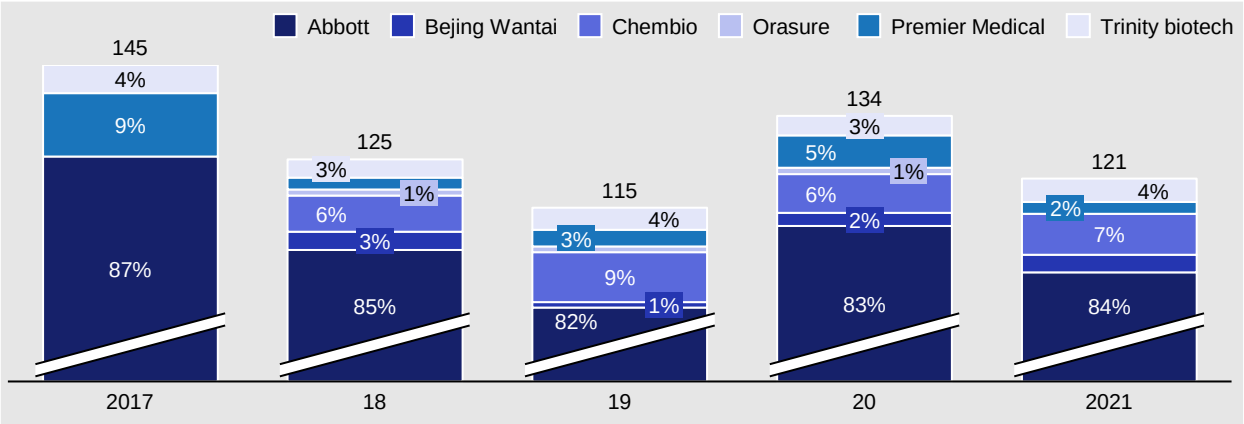
The African RDT market mainly addresses two diseases, malaria and HIV and is highly concentrated on a few number of large players

Detailed next

Malaria RDT supplier market share by volume, millions or RDTs



HIV RDT supplier market share by volume, millions or RDTs



Key insights

Both malaria and HIV RDT markets are highly concentrated markets

- This is due to **brand, IP and large-scale production**, making it difficult for new entrants

The malaria RDT market has historically been a duopoly, controlled by two large manufacturers: Abbott and Access Bio. However, **recently, more manufacturers have taken a significant market share**

- Abbott continues to obtain the largest share of malaria RDT
- The second-largest producer, Access Bio[1] has temporarily left the market, which created more room for Premier, Advy & Arkray
- Access Bio has a local manufacturing facility in Ethiopia, which has WHO-PQ approval and fully exports its production

The HIV RDT market is a monopoly, with Abbott controlling >80% of the market

- This is mainly **due to the existence of relatively fixed testing algorithms** which specifies specific brands and technologies and are generally favouring Abbott products
- Additionally, **products and technology are protected by IP**, which reduces competition

Donors are pushing for diversification of products as well as local production

- **PEPFAR has committed to buy 15m HIV RDTs** from African manufacturers over the next 5 years

1. Access Bio had a large share of the malaria RDT market, but has recently left the market to focus on COVID RDTs

Source: Malaria diagnostics market and technology landscape, Geneva: Unitaid. 2022, HIV RDT market landscape, WHO, 2023, https://www.state.gov/pepfar-sets-bold-manufacturing-targets-for-africa/

HIV RDTs are dependent on testing algorithms, which are typically done in 3 stages and brands are selected as algorithms are developed

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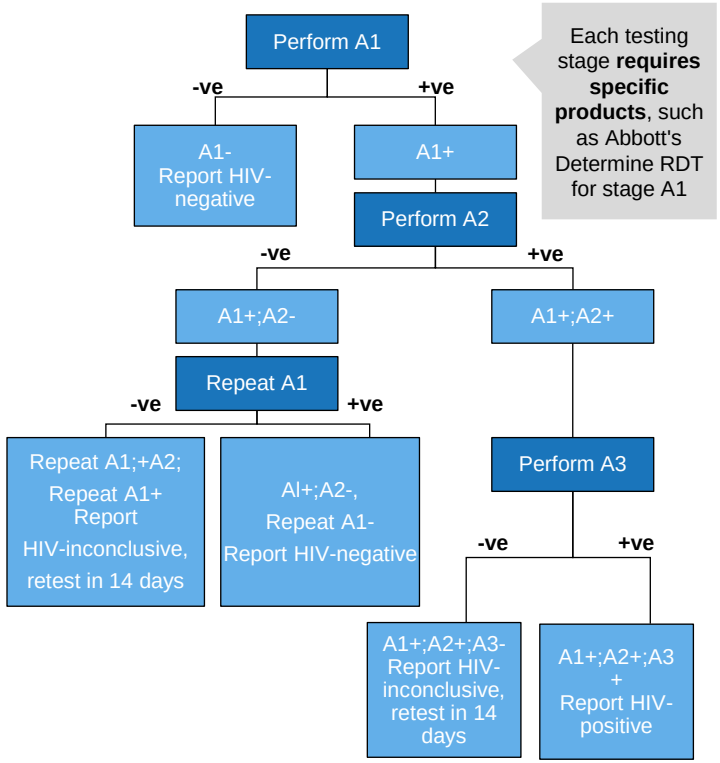
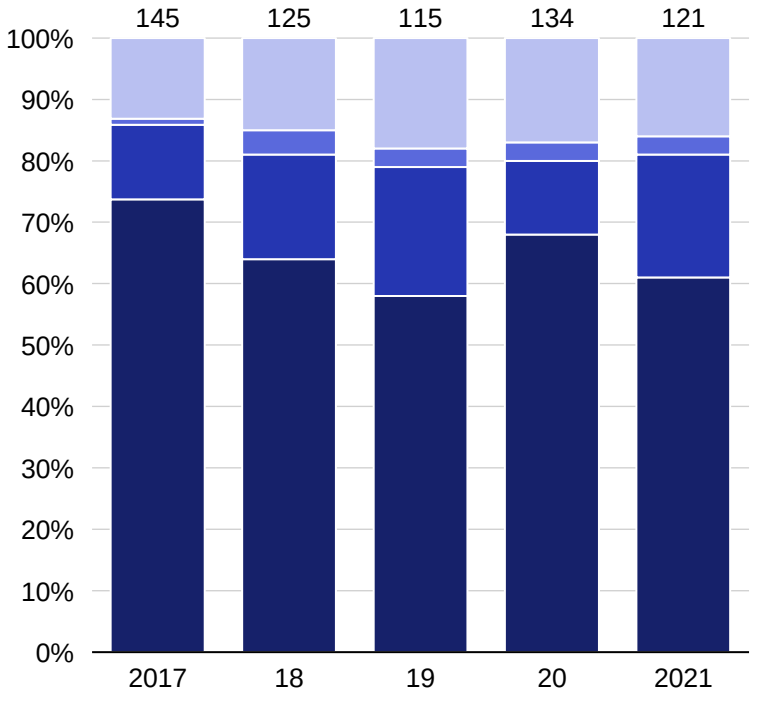
Determine
Bioline
Determine (Ag/Ab)
} **Abbott products**
Other manufacturers

WHO recommendation of three test algorithm for HIV diagnosis[3]



Abbott HIV RDT market share by product type, millions or RDTs



Key insights

- **Product brand is highly linked with a country's testing algorithm,** and changing product requires extensive testing and validation
  - Testing algorithm is developed to ensure accuracy
- Typically, **a test with the highest sensitivity**[1] **serves as Assay 1** ("A1"), the first test in the algorithm, to maximize HIV detection, **which often has lower specificity**[2]. Hence **A2 and A3 tests are done with by RDTs having high specificity**[2]
  - **Abbott was the first company** to get **highly sensitive RDT** WHO-PQ approved
  - **Both Determine and Bioline tests from Abbott have 100% sensitivity**, which makes them **well-suited for A1**. They also have >99% specificity making the well-sutied for other stages.
  - **Large number of countries have Abbott products in their algorithms and haven't changed brands**, since that requires a high amount of testing and validation

1. Highly sensitive RDTs are tests that are good at capturing true positive cases, minimizing the number of false negatives. However, they can sometimes capture false positives, which are addressed by RDTs with high specificity
2. RDTs with high specificity are tests that are effective at excluding individuals who do not have the target condition, minimizing the number of false positives
3. WHO recommends 3-level testing for high accuracy, and countries have to design their own algorithm and select products that fit them on their own. WHO's minimum acceptable performance for an individual test is >99% sensitivity and >98% specificity, which Abbott products meet

Source: HIV RDT market landscape, WHO, 2023, Consolidated guidelines on HIV testing services, WHO, https://www.who.int/publications/i/item/978-92-4-155058-1

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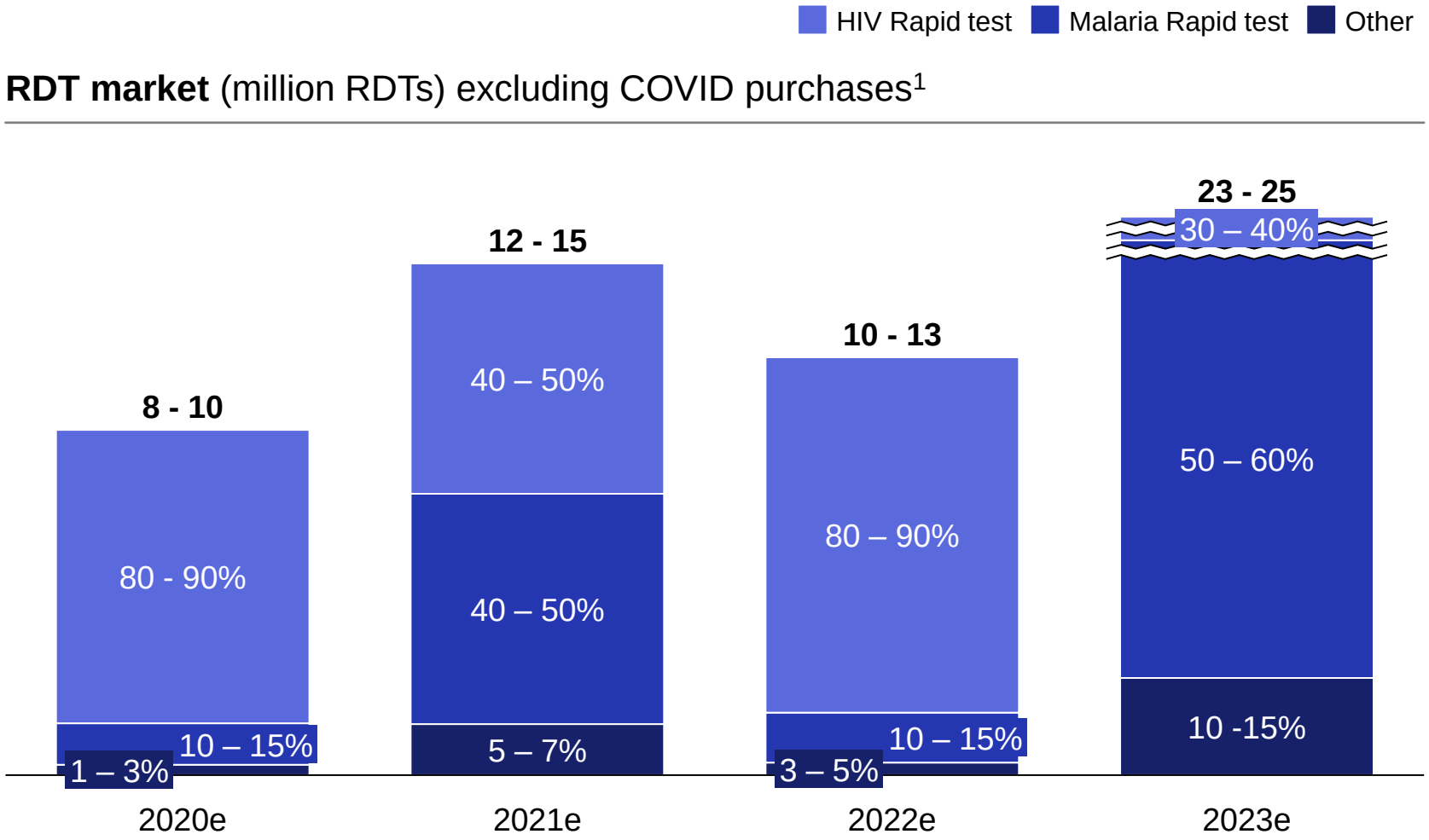
Local market of RDTs is not large enough for multiple large-scale players, requiring local manufacturers to target export markets



1. For the purpose of this analysis, private sector data was estimated. E=Estimated full-year data. Source: EPSS Procurement data (2020-2023), coherent market insights 2022 2. One of the manufacturers is Access Bio, which was the second largest manufacturer of malaria RDTs. They have obtained WHO-PQ approval and are primarily addressing export markets 3. Local manufacturers don't target the local market EPSS market and rarely participate in the bidding process. This can be because they are unable to compete with large global producers

Africa RDT market

Volume, 2022, millions of RDTS	2-3bn
Value, 2022, USD	1-2bn

Local manufacturers

Number of manufacturers[2]	2
Manufacturers supplying EPSS market[3]	0

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The overall product cost structure of RDT manufacturing has multiple important dimensions

Cost category	Subcategory	Description	Best in class share of cost, %		Ethiopia's relative cost difference
Raw material	**Strip raw material**	RDT strips such as: sample pad, absorbent pad, membrane (nitrocellulose), etc.	**40 – 50**	+	**All raw materials are imported,** and **local manufacturers will incur additional costs** due to logistics, and low-volume orders Economies of scale for raw material purchases can affect costs significantly
	Accessory material	RDT accessories: lancets, chase buffer solution, blood transfer devices etc.	**5 – 10**		
	Packaging raw material	Materials used in product packaging: product flier, box, foil sealing, etc.	**2 – 5**		
Conversion	**Labour**	Cost of operators, supervisors, production management, technicians, quality control, site maintenance, etc.	**15 – 25**	–	**Local manufacturers have advantages in conversion** since labour and utilities are cheaper in Ethiopia vs other countries where large RDT players are manufacturing from (e.g., India, South Korea, Japan, etc)
	Utilities	Utilities (electricity, gas, water), consumables, lubricants, QC lab glass and reagents, etc.	**2 – 5**		
	Maintenance and fixed OH	Annual depreciation of machines, land, building	**5 – 12**		
	Other	Consumables, facilities, disposal of solvents that cannot be purified to acceptable standards	**7 – 15**		

Source: Expert interviews (former production managers and product managers at major manufacturers)

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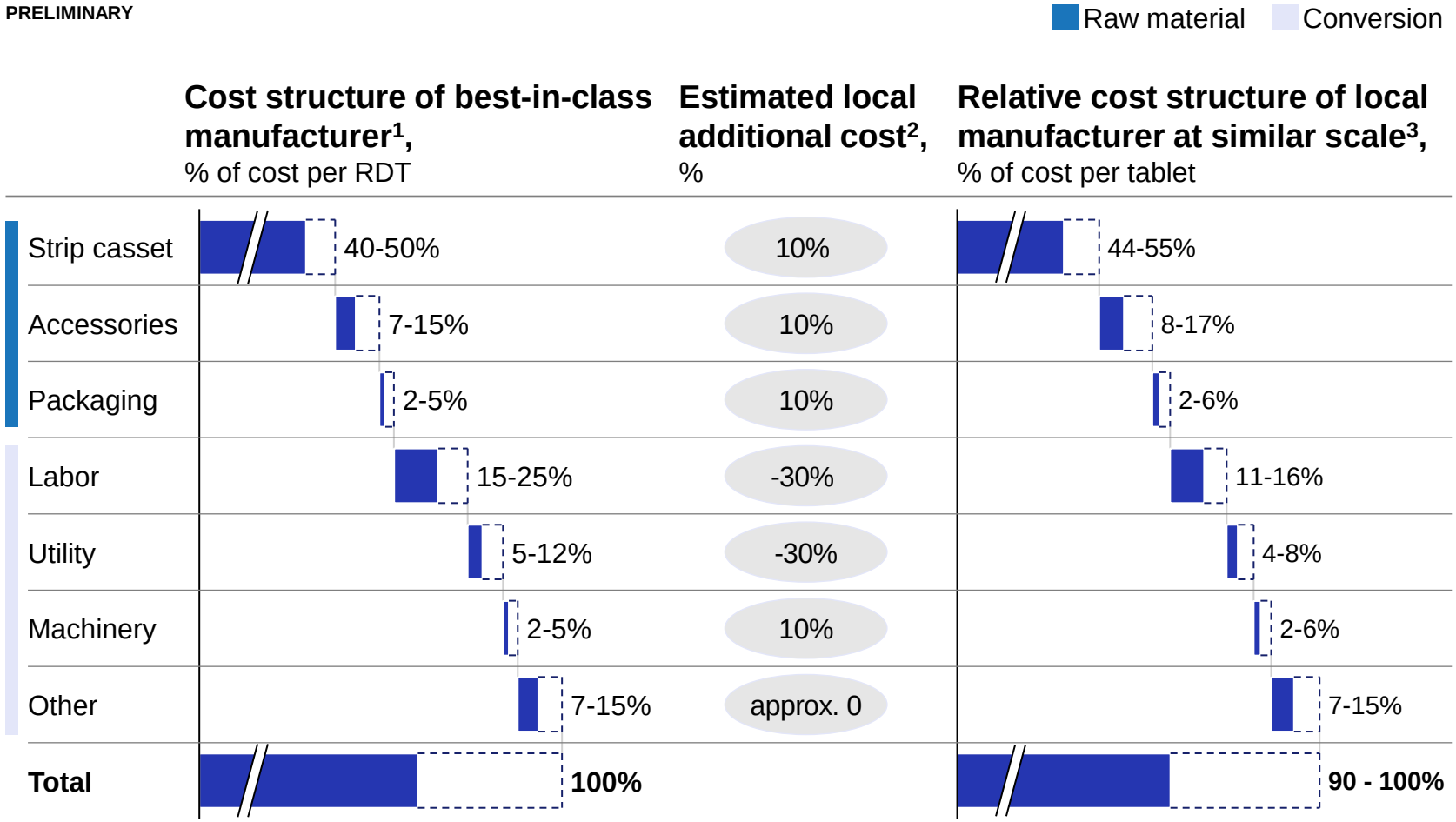
Local manufacturers can be competitive in cost for RDTs, if they achieve scale and high efficiency

PRELIMINARY



1. Best-in-class manufacturers produce >100m RDTs per year. They are also located in countries such as Japan, South Korea and India, which all have high costs of labour and services (e.g., utility)
2. Additional percentage of costs that would be added due to Ethiopian local context (e.g., logistics and monopolized raw material prices)
3. Best-case-scenario for local manufacturing at similar scale and top quartile efficiency as best in class manufacturers

Key takeaways

- If local manufacturers produce at **top performance operational efficiency and produce at a similar scale, they can be competitive** in manufacturing costs with best-in-class
  - Achieving top performance can be difficult and would take substantial time
  - Scale production has to match the market
- **Competitiveness can also improve as local conditions** such as; utility stability and labour productivity **improve**

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Long-lasting insecticide-treated nets (LLINs) don't present a substantial opportunity

Operational considerations

LLIN production process has limited operational complexities, as they are highly textile heavy industry

The only process that is pharma-related is the application of insecticide; several producers focus on textile processes, outsourcing insecticide treatment

At 10+ million units' manufacturers start closing into efficient-scale production

All raw materials are imported and take up the **largest share of cost** (insecticide, netting & packaging take ~65% of the cost)

Local context

Ethiopia has limited cost advantages, such as labour and utility, which only take up ~10% of the cost of production

Logistics costs can be higher (vs. Asia) to address regional markets since Ethiopia was worse sea freight connections

Several local textile producers can and have previously similar products, but currently, there is **no local production**

The local market in 2022 was between 30 - 35m USD, which is relatively small (~14.6m LLINs representing ~3% of global need)

Market dynamics

LLIN demand has been growing by ~10% annually in the last 5 years, and is expected to keep growing in the near future

The LLIN market is highly concentrated, eight manufacturers account for ~60% of the market

IP and branding are critical for LLINs, particularly for the insecticide APIs used in the nets for extra protection,

Most of the API production is in China and Vietnam, where it is close to the remaining raw material production (e.g., yarn)

There is one large producer in Tanzania, producing over 30m LLINs annually and addressing primarily the donor market on the continent

Donors are big buyers of LLIN, procuring >85% of global procurement, and the most important factors for them are **quality** (and **time of delivery**

High share of donor demand highlights the **criticality of obtaining WHO-PQ for the products**

Key insights

- **Ethiopian will not likely be an industry leader for LLINs** since the local market is not large enough to achieve scale, and export logistics are not advantageous
- **The business case for LLINs could be focused on import substitution**, but only up to 25% of local value-add would be expected
- Given the criticality of API IPs and branding, **partnerships with API producers should be in place**
  - **Future guarantee commitment can be used** to stimulate investments and attract these prominent players
- **Integration of industry with the current capacity in textiles** can support the development of LLINs
  - **There are two manufacturing options:** 1) only apply insecticide while purchasing the net, or 2) purchase all raw materials

Source: expert interviews, industry estimates, company reports, EPSS

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There are different types of long-lasting insecticide-treated nets (LLINs) in the market, varying by net material and insecticide treatment

Types of LLINs vary by material...

Polyester	Polyester nets are coated with a suspension that contains the insecticide and other additives. Average mesh size is 24 holes /cm^2
Polyethylene	Polyethylene nets are incorporated with active ingredient. Insecticide content is typically ~30% higher, and average mesh size is 9 holes/com^2

… and class of insecticides used for treatment

Pyrethroids	Commonly used pyrethroids include; permethrin. Alpha- cypermethrin, and deltamethrin There has been a decline in efficacy of LLINs from resistance built up by the mosquitoes
Pyrethroids + Piperonyl butoxide (PBO)	Piperonyl butoxide (PBO) is a synergist typically combined with pyrethroids to increase mosquito susceptibility
Dual active ingredients (A1)	Some LLINs are treated with 2 insecticides (e.g.. pyrethroid and chlorfenapyr) to further increase the efficacy of the nets

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LLIN manufacturing can be shown broadly in 3 macro steps; upstream, midstream and downstream productions

Description						
Main APIs involved in LLIN production are pyrethroids and piperonyl Butoxide Involves synthesizing the insecticidal agent to increase prevention of mosquito bites	Fibers are spun and twisted together to create a durable and versatile material that serves as the foundation for weaving Polyester or polyethylene yarn materials are used	Yarn is wound around warping beams, then knit using the warp knitting machine The forming is the basis for the net's design	Some nets go through a dying machine to change colour (except white nets) This is to achieve the desired hue, which enhances visual appeal and ensures durability and longevity	Knitted and dyed fabric is then placed in a heat-pressing machine to ensure it holds its shape	Nets are pushed through an insecticide chemical bath to coat it, then this is placed in a drying chamber	Involves cutting the woven material into the desired sizes, sewing the pieces together to form the final net structure, and packaging the finished nets.

1. Most players outsource dying due to specialized equipment required

Source: Company Websites, WHO Public Inspection Reports, Press search

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There are typically two approaches that local manufacturers can target based on the different stages of the production process

	Approach 1: downstream	Approach 2: midstream and downstream
Overview	Local manufacturers can **specialize in the downstream manufacturing process**, **handling the final treatment, cutting, sewing, and packaging**. The majority of **midstream processes are outsourced**, and pre-treated/treated nets are procured for the final set of steps.	Manufacturers can adopt a comprehensive approach to **specialize in both midstream and downstream production**, overseeing both processes. Manufacturers **would be integrated** and would **source raw materials for the midstream processes**
How to make it work	Manufacturers **create partnerships with large global LLIN manufacturers**, that are upwards integrated, to import pre-treated/treated nets. This will allow local producers to **minimize capex, while only performing fewer complex processes** but local value addition can be limited	Partnerships would primarily only be **necessary with other LLIN manufacturers for API procurement**. Other partnerships with **textile industries can also be present to source the textile inputs.** This allows for **greater control over the manufacturing stages**, ensuring a seamless and efficient production LLINs.
Pros/ Cons	⊕ Less complex manufacturing process ⊕ Cost saving and less CAPEX spending ⊕ Efficiency due to downstream specialization ⊖ No cost integration benefit ⊖ High dependence on external partners ⊖ Less control over midstream processes and product quality	⊕ Less control over midstream processes and product quality ⊕ Cost benefits due to integration ⊖ Higher initial investment in CAPEX ⊖ More complex logistics, production and coordination

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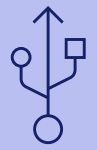
Generally, there are some key operational considerations to have in mind when developing a LLIN business case



Manufacturing process

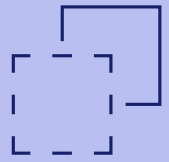
The LLIN **manufacturing process is not highly complex** in comparison to other pharma manufacturing processes and is a textile-heavy industry

Manufacturing approach

Manufacturers can select different approaches to manufacturing LLINs, which can affect costs and level of control in manufacturing. This can be selected by assessing different factors such as supply chain and sourcing advantages

Quality

Quality and regulatory approvals are important for LLINs, to ensure the effectiveness and safety of the nets. Typically, LLINs are **effective for 3 years**, even after repeated washing



Product variety

Brands matter, particularly for **the design, materials, and insecticidal treatments** of LLINs, which are typically IP-protected

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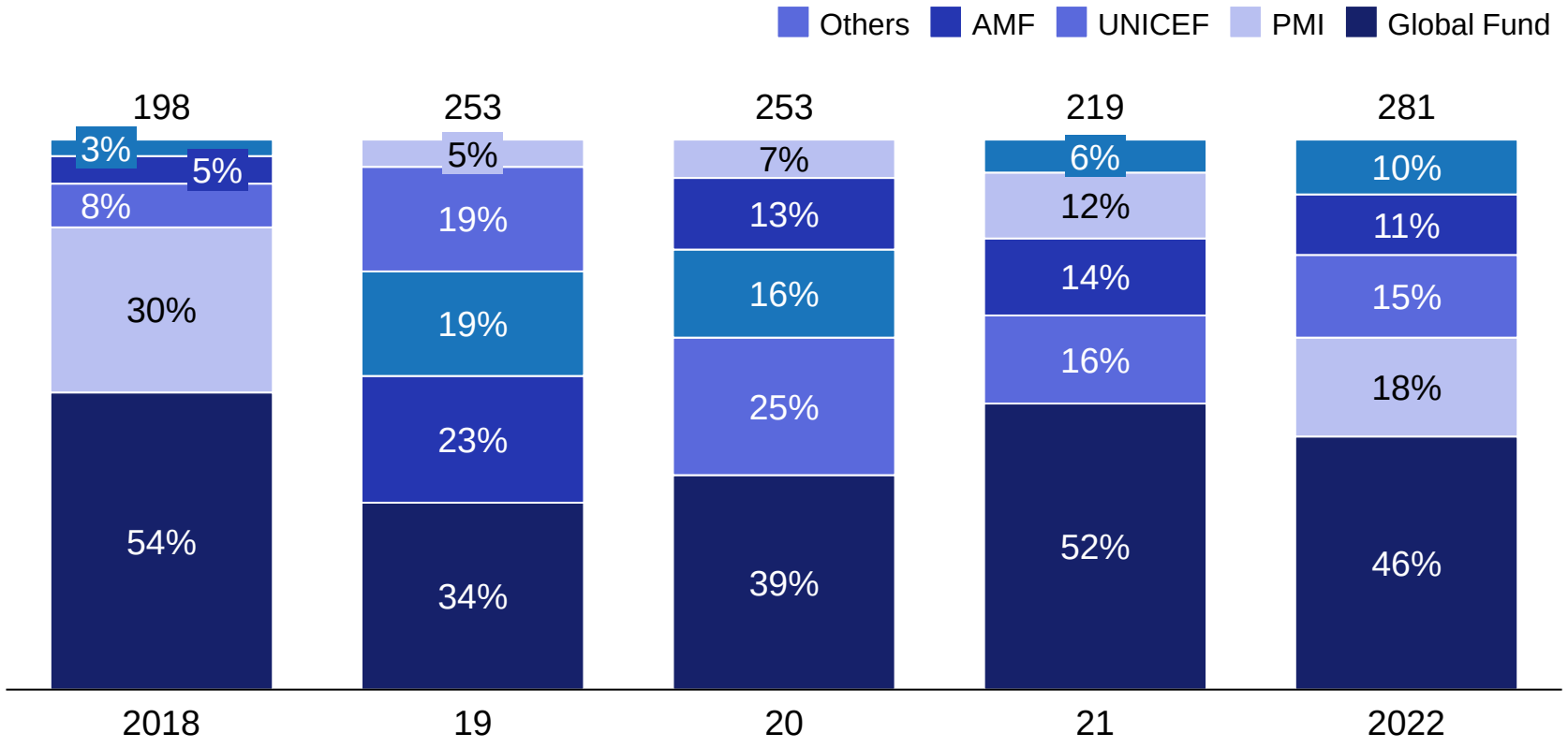
85% of global LLIN procurement between 2018 and 2022 was supplied by four main donor organizations

Global supply of LLINs by supplier organization, Million nets, 2018 - 2022



Source: Company Annual Reports, Net Mapping Project

Key takeaways

Global Fund is the largest LLIN funder, accounting for 44% of the global procurement from 2018-2022

Potential local LLIN producers planning to supply to the local and export markets **should collaborate with donors to guarantee market**

Donors are highly focused on quality and ability to deliver products on time of distribution season

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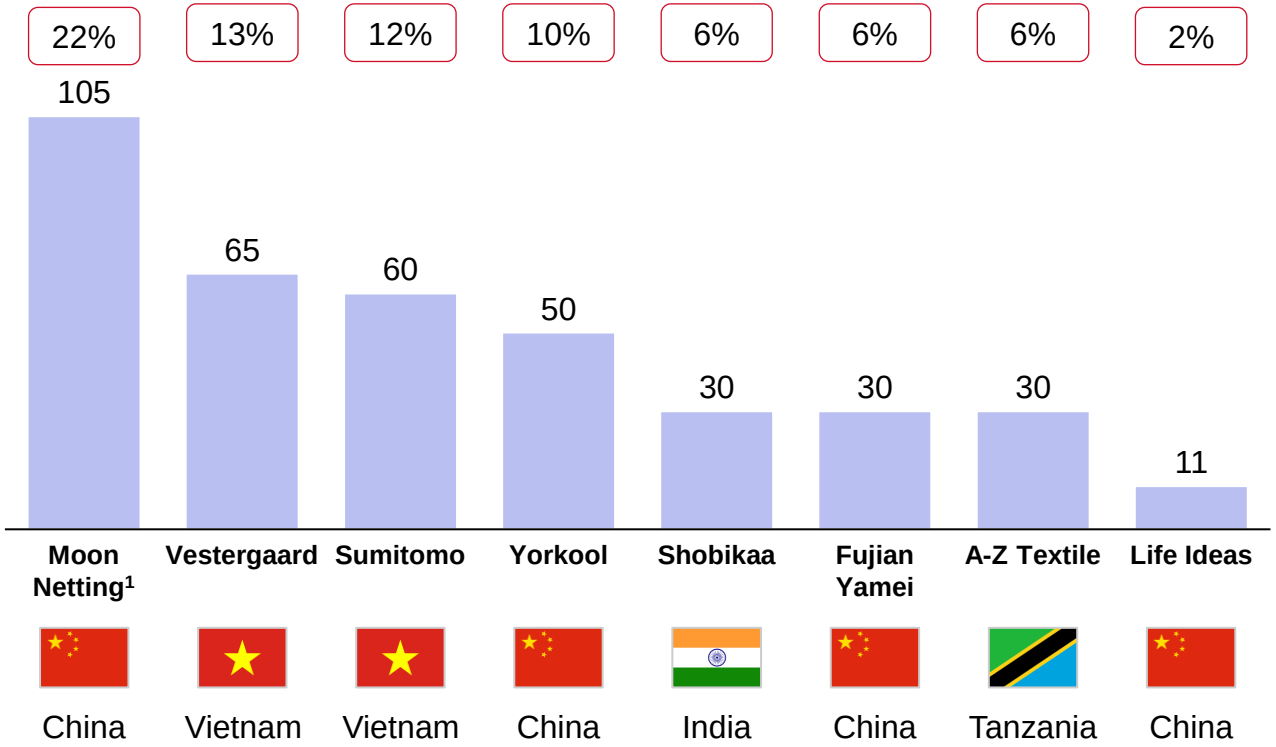
Eight manufacturers account for ~80% of the total global LLIN market, and close to 40% of the global manufacturing capacity is not utilized

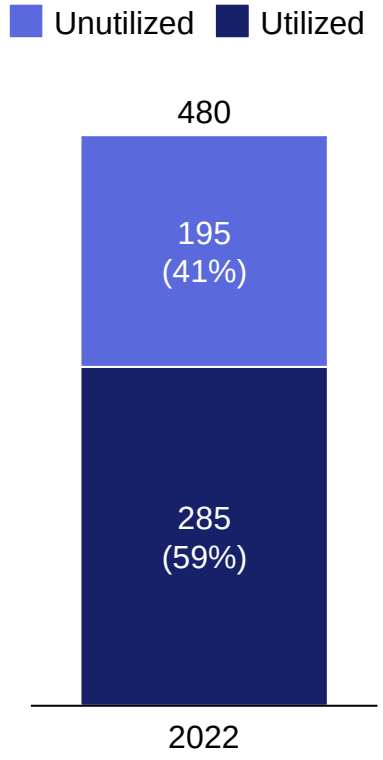
LLINs production capacity, Mn nets, 2022

X% Share of the total global LLIN market

Top eight suppliers



Utilization rate



Key takeaways

The global LLIN market is highly consolidated, **creating a huge barrier for new entrants**

The global LLIN production capacity is higher than the current demand, **leading to only 60% capacity utilization**

China and Vietnam manufacturers account for **65%** of the total global market while **Africa** accounts **only for 6%**

1. Formerly named TANA Netting

Source: Company reports, Press search

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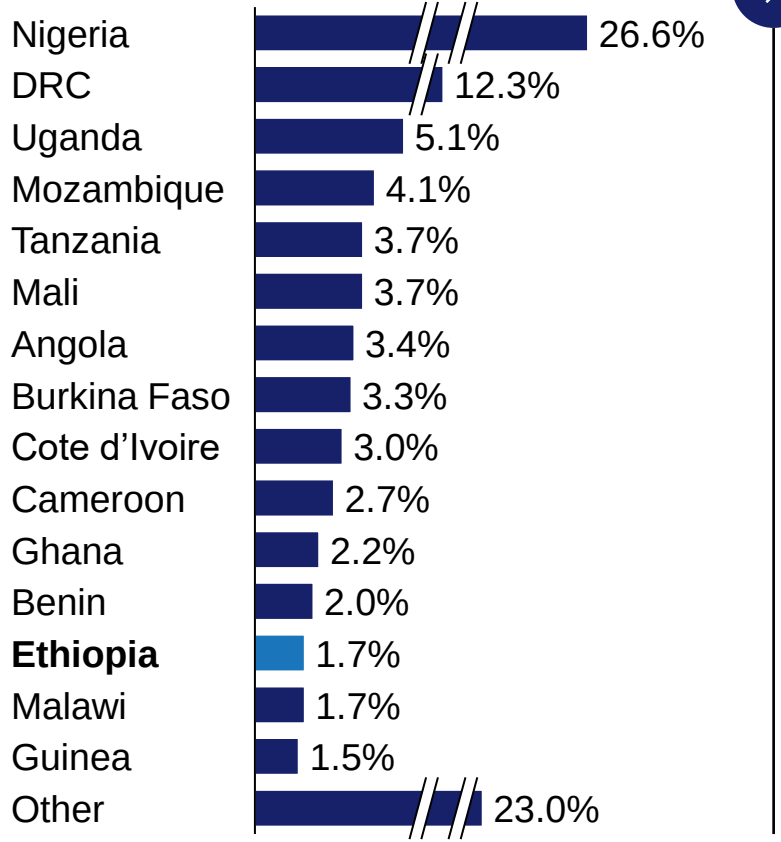
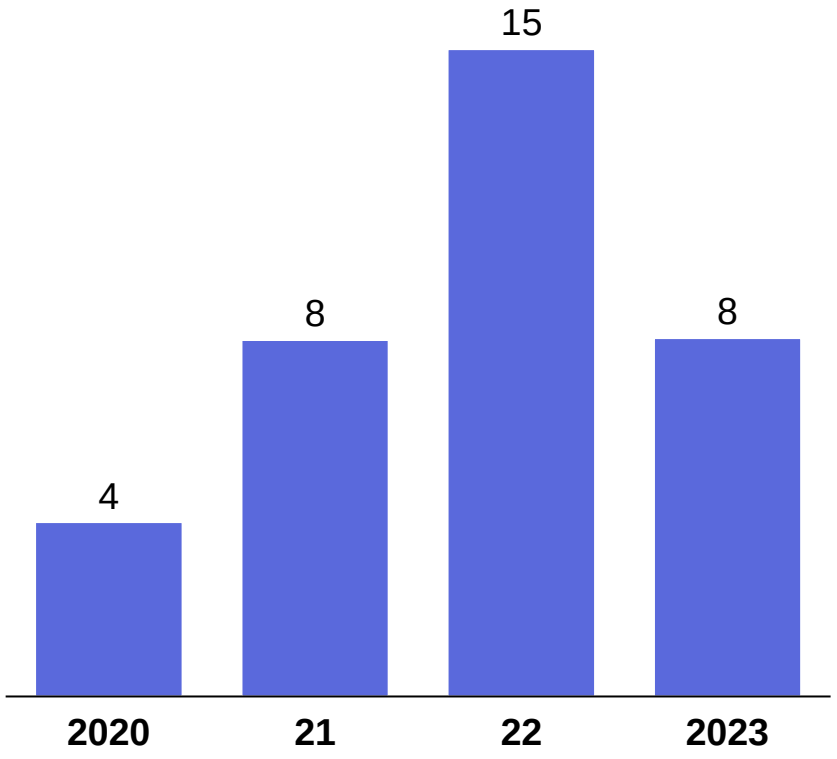
Ethiopia's total demand could be sufficient to create one local producer with enough volumes to make it a top 10 global producer

Malaria cases, % of the global total, 2021



Ethiopia bed nets demand, Mn units, 2020-2023



Source: EPSS

Key takeaways

Malaria cases in Ethiopia are low compared to Nigeria, 1.7% vs 26.6%

The malaria RDT market in Ethiopia is small compared to the global market

Ethiopia's local bed net market was (15 Mn units in 2022 higher than the total production capacity of Life Ideas (8 Mn units), the world's eighth-largest producer Leveraging, seeming to indicate that **local demand might be enough to generate a relatively high level of economies of scale**

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The overall product cost structure of RDT manufacturing has multiple important dimensions

Cost category	Subcategory	Description	Best in class share of cost, %	Ethiopia's relative cost difference
Raw material	**Insecticide/API**	Chemical substances, used in the treatment of LLINs to repel and kill mosquitoes, preventing diseases	**10 – 15%**	Imported **raw materials impose costs** on local manufacturers, due to logistics **This can also look different among different manufacturers** based on their approaches
	Netting material	Fabric or material made from polyester or polyethylene, forming the mesh structure of LLINs for physical barrier	**40 – 50%**	
	Packaging	Packaging material of finalized LLINs for distribution ensuring they are intact as they reach end-users	**10 – 15%**	
Conversion	**Labour**	Cost of operators, supervisors, production management, technicians, quality control, site maintenance, etc.	**3 – 8%**	**Local manufacturers in Ethiopia benefit from cost advantages in the conversion process**, as labour and utilities are more economical compared to other countries
	Utilities	Utilities (electricity, gas, water), consumables, lubricants, QC lab glass and reagents, etc.	**3 – 8%**	
	Machinery	Annual depreciation of machines, land, building	**5 – 10%**	
	Other costs	Facilities, overhead and other related costs	**10 – 15%**	

Source: Expert interviews (former production managers and product managers at major manufacturers)

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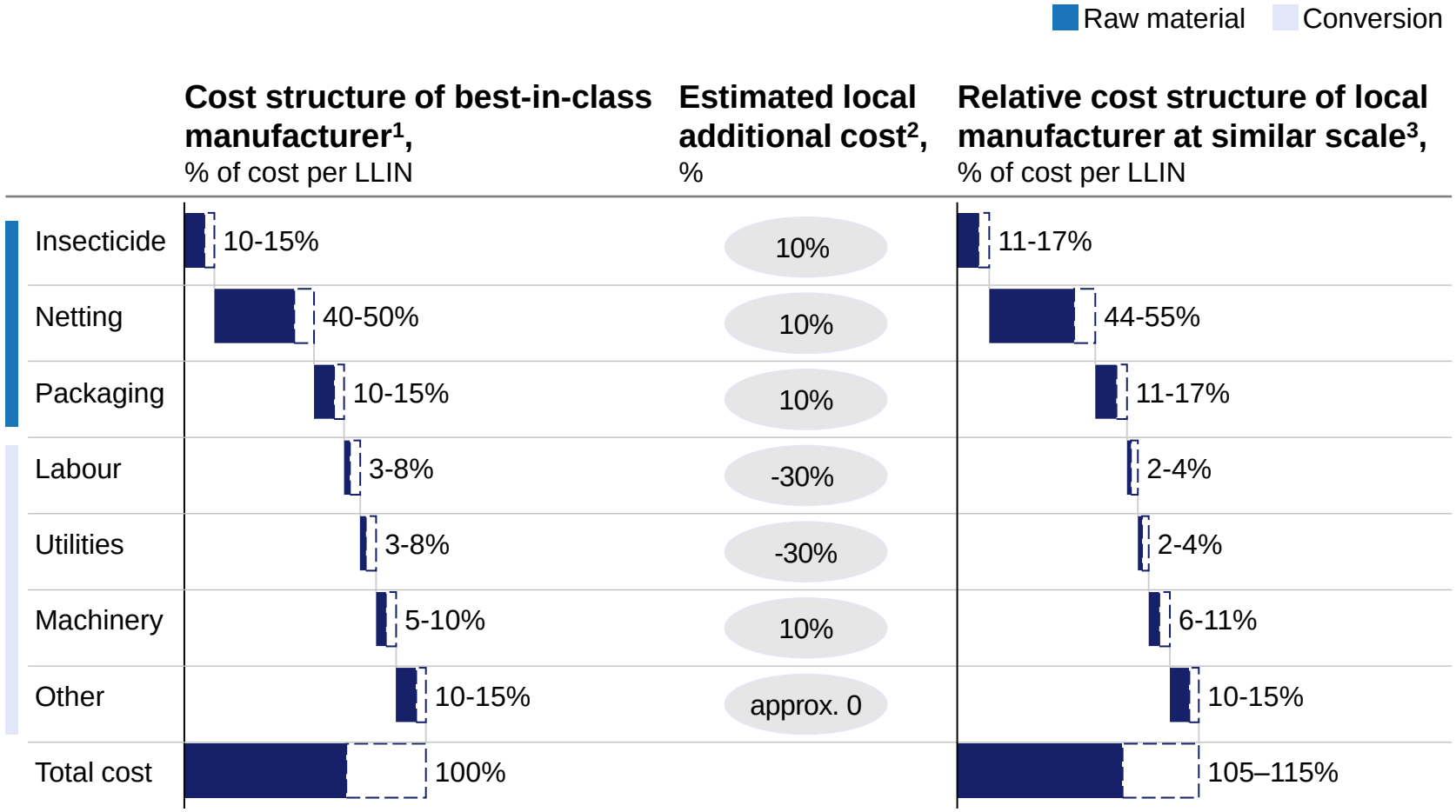
Ethiopia can target import substitution for LLINs but it is unlikely to create a competitive export industry



Source: Expert interviews, Industry estimates

Key takeaways

Raw materials account for ~70% of the costs and **the conversion cost overall is low**

- **Ethiopia's advantage in labour and utilities has less impact** because local value additions are limited

Ethiopia can potentially target import substitution by addressing the local market

- The local demand can be substituted by 1-2 large-scale manufacturers

It would be **difficult and unlikely to become an exporter** unless there is a raw material local integration