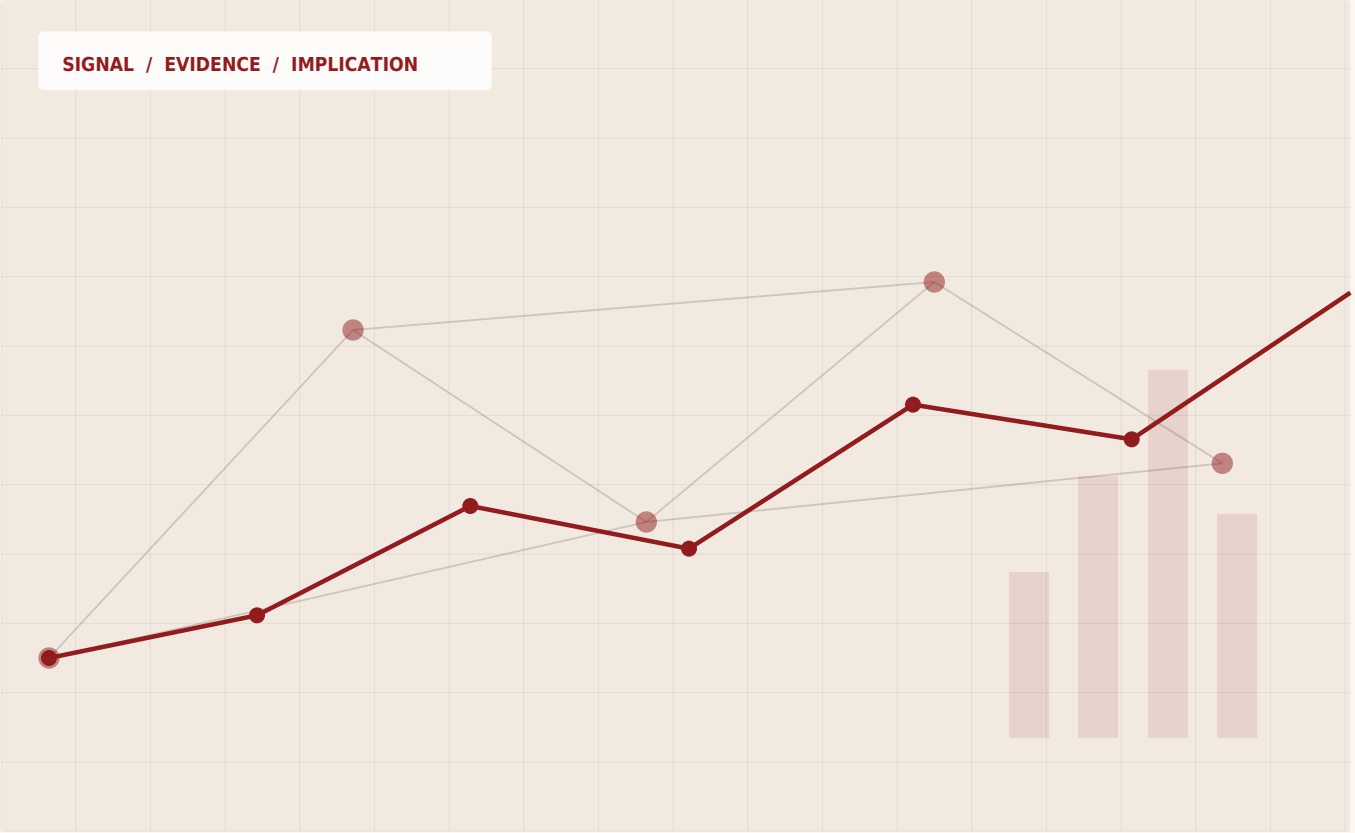
HEALTH / INVESTMENT / INDUSTRY

SECTOR BRIEF / JUNE 2026

Ethiopia's Pharmaceutical Investment Case

Import Dependence, Local Manufacturing, WHO Maturity Level 3, and the Capacity-Utilisation Gap



KEY INDICATORS AT A GLANCE

$676M **Pharma imports (2023)** *COMTRADE / UN Trade Statistics 2023*	**40%+** **Local supply share (2026)** *World Bank / EFDA, May 2026*	**$1.8B** **Market size (2025 proj.)** *EIC; 15% annual growth (5-yr avg)*	**$4B** **Market target by 2030** *EIC projection; UNECA benchmark*
$500M **Liaoning Fangda (MOU)** *EIC Forum, March 27, 2026*	**29%** **Capacity utilisation** *Domestic manufacturers, Jan 2026*	**ML3** **WHO regulatory status** *EFDA; confirmed Sept 2025*	**~30** **Kilinto investors** *Active/construction; World Bank, May 2026*

DATA INTEGRITY NOTE *The $676M import figure is from UN COMTRADE (2023), the most recent verified annual data available. The 40% local supply share is from World Bank/EFDA (May 2026). Market projections ($1.8B by 2025; $4B by 2030) are EIC projections, not actuals. The Liaoning Fangda $500M commitment is a forum-stage MoU confirmed by the EIC (March 27, 2026); no executed commercial agreement or commissioned plant has been reported. Single-source claims are flagged inline.*

01 THE MARKET: SIZE, GROWTH, AND THE IMPORT DEPENDENCY FACT

Ethiopia Imports $676 Million in Medicines Per Year. That Is the Baseline Investment Case.

Ethiopia spent $676.7 million importing pharmaceutical products in 2023, according to UN COMTRADE data. That figure represents the current cost of import dependency, not a ceiling on demand. The domestic pharmaceutical market has been growing at an average of 15% annually for the past five years and is projected to reach $1.8 billion in 2025 and $4 billion by 2030, according to the Ethiopian Investment Commission. A market growing at 15% annually doubles in under five years.

- **THE STRUCTURAL DRIVER:** Ethiopia's population of 130 million is young, urbanising at 5.4% annually, and experiencing rising rates of non-communicable disease diagnosis alongside the persistent burden of communicable diseases including malaria, HIV/AIDS, and tuberculosis. Healthcare access is expanding, government health spending is rising, and awareness of treatment options is increasing. All four demand drivers point in the same direction.
- **THE IMPORT CONCENTRATION RISK:** Imports account for between 65% and 75% of the Ethiopian pharmaceutical market, sourced primarily from India (22%), Netherlands (20%), and Belgium (13%), according to market intelligence data. The COVID-19 pandemic made this exposure concrete: supply chains to Ethiopia were disrupted in exactly the moments domestic supply was most critical. That episode accelerated the government's policy commitment to local manufacturing as a matter of health security, not only economics.
- **THE PEER BENCHMARK:** Kenya, the regional leader in East African pharmaceutical manufacturing, supplies approximately 30% of its domestic market from local production. Ethiopia, at a stated 40% local supply share as of May 2026 (World Bank/EFDA), has surpassed that benchmark on paper. However, capacity utilisation among domestic manufacturers stands at only 29% as of January 2026 (New Business Ethiopia, April 2026). The gap is not capacity. It is production quality, GMP compliance, and raw material access.

02 THE REGULATORY TRANSFORMATION: WHO ML3 AND WHAT IT ACTUALLY UNLOCKS

September 2025: The Regulatory Milestone That Changes the Export Conversation.

In September 2025, EFDA completed a comprehensive WHO assessment using the Global Benchmarking Tool, evaluating regulatory systems against more than 250 indicators. The result: WHO Maturity Level 3 (ML3) status, confirmed by WHO on September 30, 2025. Ethiopia became the ninth African country to reach this level, joining Egypt, Ghana, Nigeria, South Africa, Tanzania, Zimbabwe, Senegal, and Rwanda. Kenya has not yet achieved ML3.

- **WHAT ML3 MEANS IN PRACTICE:** Maturity Level 3 is defined by WHO as a stable, well-functioning, and integrated regulatory system, with confirmed capacity to authorise medical products, conduct market surveillance, and monitor safety events effectively. For manufacturers, EFDA-approved products can be exported to markets that recognise WHO ML3 as a quality assurance proxy. For investors, the regulatory risk premium on Ethiopia as a manufacturing base has structurally declined. Dr Mohamed Yakub Janabi, WHO Regional Director for Africa, described the achievement as a foundation for universal health coverage.
- **THE ML4 PATH:** Maturity Level 4 signifies an advanced regulatory system committed to ongoing improvement. EFDA has explicitly targeted ML4 eligibility and is positioned for progression toward WHO Listed Authority (WLA) status, which would further expand export markets accessible to Ethiopia-manufactured medicines. No public timeline has been confirmed for either milestone.
- **COUNTER-ARGUMENT: REGULATORY PROGRESS VERSUS MANUFACTURING REALITY:** A rigorous regulatory system is a necessary condition for pharmaceutical manufacturing investment, not a sufficient one. As of January 2026, only 33.3% of domestic drug manufacturers held current Good Manufacturing Practice (cGMP) certification, according to an Addis Ababa University study (Anley et al., 2025, PLOS Global Public Health). The regulatory framework is now internationally credible. The manufacturing base has not yet caught up.

> **INVESTOR RELEVANCE**
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> WHO ML3 status is a material input to investment decisions in pharmaceutical manufacturing. It confirms that EFDA-approved products meet the threshold required for export to regional markets. For manufacturers targeting the broader African market through Ethiopia's AfCFTA position and Ethiopian Airlines cargo network, ML3 removes one of the key barriers that previously constrained the export case. It does not resolve the GMP compliance gap among existing domestic producers.

03 KILINTO SPECIAL ECONOMIC ZONE: THE INFRASTRUCTURE BET

279 Hectares. Purpose-Built. Nearly 30 Investors at Various Stages. The Case and the Gaps.

Kilinto Special Economic Zone (SEZ) is a 279-hectare dedicated pharmaceutical and medical equipment manufacturing hub in Akaki-Kaliti sub-city, approximately 25 kilometres from central Addis Ababa. Fully financed by the World Bank and developed in two phases with the Industrial Parks Development Corporation (IPDC), the park has approximately 30 investors at stages ranging from factory construction to active commercial production, according to the World Bank (May 26, 2026).

- **WHAT KILINTO PROVIDES:** Integrated pharmaceutical-grade infrastructure: dedicated power substation, state-of-the-art wastewater treatment plant, reliable water supply, 18 kilometres of asphalt road, GMP-compliant zoning with segregation and contamination controls, ready-made factory spaces, business centres, and warehousing.

The IFC has highlighted the park as a model initiative. For incoming manufacturers, the ready-built infrastructure meaningfully reduces upfront capital requirements relative to greenfield site development.

- **CAPACITY AND SCALE:** At full build-out, Kilinto is designed to accommodate more than 1,000 factories across its 166 hectares of dedicated manufacturing land. Ten global companies signed MoUs with the EIC to establish factories in the park, with Chinese manufacturers representing the most active group. Sansheng Pharmaceuticals Plc, which inaugurated its production plant in Ethiopia in June 2018 inside the Eastern Industry Zone, represents the established Chinese manufacturing presence. Kilinto is intended to consolidate and expand this base.
- **THE LIAONING FANGDA COMMITMENT:** Liaoning Fangda Group Industrial Co., Ltd. committed $500 million at the Invest in Ethiopia 2026 Forum (March 27, 2026) for combined steel and pharmaceutical manufacturing plants. The commitment is an MoU at forum stage, confirmed by the EIC and widely reported across Reuters, MarketScreener, and ATQ News. The specific allocation between steel and pharmaceutical components, the site designation, and the commissioning timeline are not yet in the public record. Forum-stage MoUs require tracking through to executed commercial agreements before being treated as deployed capital.
- **THE INFRASTRUCTURE GAP THAT KILINTO DOES NOT CLOSE:** Cold chain logistics. Pharmaceutical manufacturing requires temperature-controlled storage and distribution throughout the supply chain. Ethiopia's cold chain infrastructure outside Addis Ababa remains underdeveloped. For manufacturers producing vaccines, biologics, or temperature-sensitive generics, cold chain coverage is a constraint that Kilinto's internal infrastructure does not resolve. This is a named structural risk for the sector's export ambition.

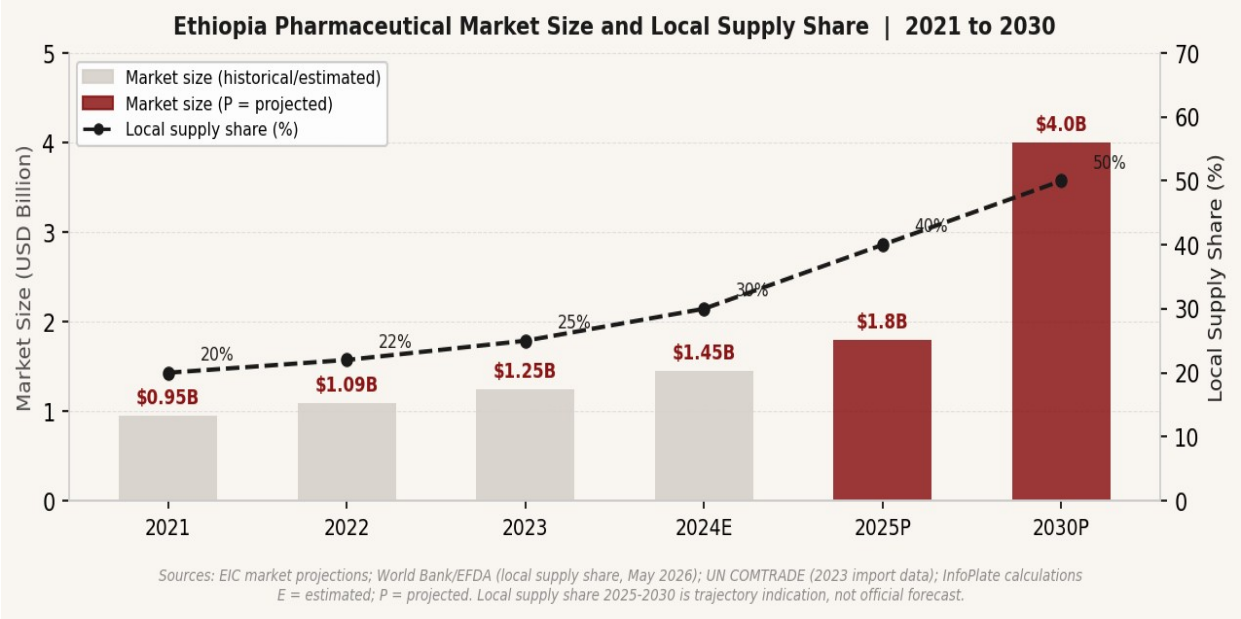

Figure 1: Ethiopia Pharmaceutical Market Size and Local Supply Share | Sources: EIC; World Bank/EFDA (May 2026); UN COMTRADE 2023; InfoPlate calculations

04 STRUCTURAL RISKS: THE FOUR GAPS THAT DETERMINE WHETHER THE STORY HOLDS

The Market Is Real. The Regulatory Foundation Is Solid. Four Structural Gaps Still Determine the Outcome.

The investment case for Ethiopian pharmaceutical manufacturing is supported by genuine fundamentals: a large and growing market, an internationally credible regulatory framework, purpose-built infrastructure, and a government with a demonstrated policy commitment. The counter-case is not that the fundamentals are weak. It is that four structural gaps separate the current position from realised manufacturing scale.

- **GAP 1: NO ACTIVE PHARMACEUTICAL INGREDIENT (API) MANUFACTURING:** Ethiopia has no API manufacturers. The country relies entirely on imported active ingredients. Without domestic API production, local pharmaceutical manufacturing remains in formulation and packaging, not deep-value manufacturing. API manufacturing requires high capital investment, specialised technical capability, and extended lead times. No investment commitment in the current pipeline has named API manufacturing as its primary focus.
- **GAP 2: GMP COMPLIANCE AMONG EXISTING PRODUCERS:** As of 2020, only 33.3% of domestic drug manufacturers held cGMP certification (Addis Ababa University, Anley et al., 2025). The EFDA has made GMP compliance a stated priority, and the regulatory ML3 achievement creates the institutional framework for enforcement. Closing the compliance gap requires manufacturer investment in processes and equipment, not only regulatory action.
- **GAP 3: POWER SUPPLY RELIABILITY:** Insufficient and inconsistent power supply is described as one of the most significant production-related challenges by pharmaceutical manufacturers operating in Ethiopia (The Global Economics, June 2026). Pharmaceutical production requires reliable, uninterrupted power. Ethiopia's grid is growing through hydroelectric and renewables investment, but reliability at the plant level remains a material operating risk, particularly outside Addis Ababa.
- **GAP 4: COLD CHAIN COVERAGE:** The absence of a developed cold chain network outside major urban centres constrains both domestic distribution of temperature-sensitive medicines and the logistics viability of export at scale. Ethiopian Airlines Group's cargo network provides a meaningful partial solution for export logistics. It does not resolve last-mile cold chain requirements for domestic distribution.

THE HONEST ASSESSMENT

Ethiopia's pharmaceutical manufacturing story has a credible foundation in regulation, infrastructure, and market size. The WHO ML3 milestone is not promotional language: it is a genuine regulatory achievement that materially reduces investor risk. The four gaps are equally real. An investor entering this sector needs to underwrite the GMP compliance journey, the power supply risk, the API sourcing cost, and the cold chain build-out. None of these are disqualifying. All of them require explicit project-level capital allocation.

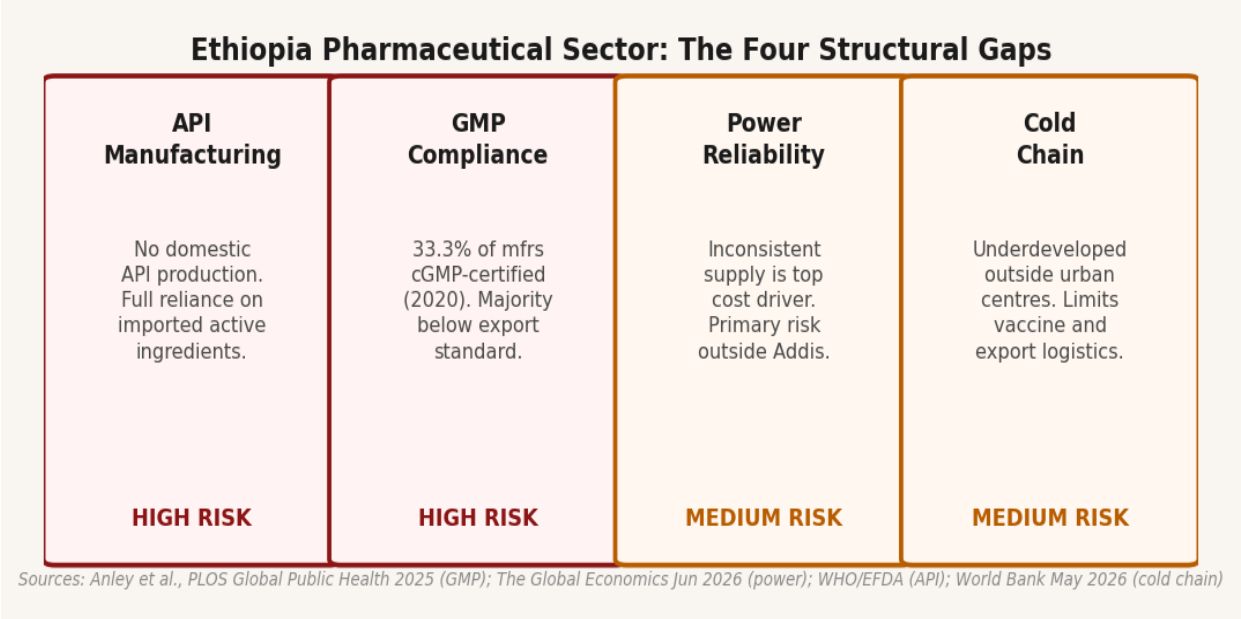

Figure 2: The Four Structural Gaps | Sources: Anley et al. PLOS Global Public Health 2025; The Global Economics Jun 2026; WHO/EFDA; World Bank May 2026

05 EDITOR'S OUTLOOK

Ethiopia's Pharmaceutical Opportunity Is Real. The Distance Between Opportunity and Outcome Requires Honest Navigation.

THE BOTTOM LINE

Ethiopia imports $676 million in pharmaceutical products annually from a market growing at 15% per year toward a $4 billion target by 2030. It has WHO Maturity Level 3 regulatory status, a purpose-built 279-hectare SEZ with approximately 30 active investors, a $500 million MoU from Liaoning Fangda Group, and a government with a consistent decade-long policy commitment to pharmaceutical manufacturing. The Kilinto park provides infrastructure that meaningfully reduces entry barriers. The EFDA's ML3 achievement confirms that regulatory risk has structurally declined. The gaps are equally named: no API manufacturing base, 29% capacity utilisation among domestic producers, 33.3% GMP compliance among existing manufacturers, an underdeveloped cold chain outside Addis, and power supply reliability as an operational variable. The $500 million Fangda commitment is an MoU at forum stage, not a commissioned plant. For investors allocating capital to this sector: the fundamentals support entry. The execution variables require project-level underwriting. The sector that delivers on its ambition will be built by manufacturers who treat the four gaps as capital allocation problems, not as risks to be noted and deferred.

Sources: UN COMTRADE (pharma import data, 2023); EIC Investment Commission (market projections, Kilinto, forum commitments, March 2026); World Bank / EFDA (ML3 status, local supply share, May 2026); WHO (ML3 announcement, September 30, 2025); Africa CDC (ML3 commentary, October 2025); New Business Ethiopia (capacity utilisation, April 2026); Anley et al., PLOS Global Public Health 2025 (GMP compliance data); Ethiopia Today / World Bank feature (June 1, 2026); The Global Economics (power supply risk, June 2026); MarketScreener / Reuters / ATQ News (Fangda MoU, March 2026); Mobility Foresights (import source data); JEPA Africa (EAC pharmaceutical benchmarks, October 2025).