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Improvements to pharmaceutical manufacturing capacity, Ethiopia

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Abstract

Problem Ethiopia's heavy dependence on imported pharmaceuticals created public health vulnerabilities, foreign exchange pressures and recurrent medicine stockouts.

Approach In 2015, Ethiopia launched a 10-year National Strategy and Plan of Action for Pharmaceutical Manufacturing Development to improve access to quality-assured medicines. The strategy, overseen by a Joint Steering Committee co-chaired by the Ministries of Health and Industry with technical assistance from the World Health Organization (WHO), combined industrial incentives, preferential centralized procurement and regulatory strengthening.

Local setting Before strategy implementation, Ethiopia had limited manufacturing capacity. Local manufacturers supplied approximately 20% of national generic medicine demand, while supply chain fragmentation and foreign exchange constraints compromised access to imported medicines.

Relevant changes By 2025, six facilities had achieved national good manufacturing practice compliance, 11 manufacturers were operational and the Ethiopian Food and Drug Authority reached WHO Maturity Level 3. Locally produced coverage of the National Essential Medicines List increased from 90 to 140 chemical entities, across 167 dosage forms, and a vaccine manufacturing initiative was launched. However, domestic supply only increased to 23% against a 60% public procurement target; active pharmaceutical ingredient production and WHO prequalification remained unachieved, and export and workforce targets were missed.

Lessons learnt Combined, the strategy's cross-sectoral governance, regulatory strengthening, preferential centralized procurement and industrial incentives advanced local production. However, foreign exchange constraints, dependence on imported raw materials and financing and capacity gaps limited progress. Future efforts should prioritize WHO prequalification, upstream manufacturing, skilled workforce development, export competitiveness and sustainable financing while maintaining patient-centred objectives.

Introduction

The first pharmaceutical manufacturing facility in Ethiopia was established in 1964.[1] Over subsequent decades the government introduced measures to regulate and stimulate the sector, most notably through Ethiopia's 1993 National Drug Policy which sought to ensure the systematic availability, accessibility and affordability of essential, safe and efficacious medicines.[1] Despite these efforts, the industry remained underdeveloped due to the absence of a comprehensive, long-term national vision and coordinated multisectoral planning.[1]

During the early 2010s, Ethiopia emerged as one of the world's fastest-growing economies, driven by state-led infrastructural investments under its first Growth and Transformation Plan.[2,3] However, local pharmaceutical production was insufficient for the rising demand, while dependence on imports posed public health, national security and economic challenges. An evaluation of the industrial baseline in 2015 revealed that domestic manufacturers met just 20% of the national demand.[4] This deficiency forced a heavy reliance on foreign suppliers for essential therapeutics, draining scarce foreign currency reserves and leaving the health-care system vulnerable to global supply chain shocks and price fluctuations. Similar dependence affected other sub-Saharan African countries. In Ghana, for example, approximately 70% of finished medicines were historically imported.[5]

In 2015, the Ethiopian government sought technical assistance from the World Health Organization (WHO) to address these vulnerabilities.[4] This collaboration resulted in the launch of a National Strategy and Plan of Action for Pharmaceutical Manufacturing Development in Ethiopia (NSPA-Pharma 2015–2025, hereafter referred to as the national strategy).[4] This paper reviews the progress, institutional upgrades and public health lessons emerging from its implementation.

Local setting

Ethiopia's rapidly growing population and dual burden of communicable and noncommunicable diseases placed increasing demands on the health system.[6] Before implementation of the 2015 strategy, medicine supply was constrained by fragmented public–private distribution networks and historically low local manufacturing capacity.[4] Public health facilities, particularly rural health centres and primary hospitals, experienced recurrent stockouts of essential medicines, compromising timely treatment and contributing to preventable health risks.[7]

Approach

The national strategy covered the pharmaceutical manufacturing ecosystem, targeting local generic manufacturers, national regulatory bodies, higher education institutions and public procurement networks.[4] The strategy integrated national public health priorities with an industrial development policy across 10 distinct strategic pillars covering quality upgrading, specialized industrial clusters, investment attraction and other measures to strengthen domestic production.[4] A high-level joint steering committee co-chaired by the State Ministers of Industry and Health, was established to align industrial incentives, regulatory enforcements and licensing, import privileges, and public health requirements. To secure market volume and certainty of demand for domestic firms, the strategy leveraged the Ethiopian Pharmaceuticals Supply Service's centralized procurement system, which manages over 70% of public sector medicine procurement.[4] Financial incentives included extended corporate tax holidays, expedited customs clearance for raw materials, and a mandatory 25% price preference (under which the procurement agency tolerates up to 25% higher prices from local producers as compared to imported products) for domestic firms participating in public tenders.[1,4]

The strategy prioritized generic production to optimize national cost–effectiveness, reduce regulatory complexities, and address major therapeutic needs, backed by technical training from international partners such as WHO's Local Production and Assistance Unit, the United States Agency for International Development and the United Nations Industrial Development Organization.[4] By comparison, regional peers used alternative protectionist policy mixes; for instance, to protect its domestic manufacturers from low-cost Asian imports,

Relevant changes

Progress against targets

As summarized in Table 1, quantitative indicators show mixed progress over the 10-year implementation period. A major achievement was the establishment of the specialized Kilinto Pharmaceutical Industrial Park, providing dedicated infrastructure and services to reduce manufacturing investment and operational barriers. Currently, 11 companies manufacture finished formulations, and one manufactures empty hard gelatine capsules across 13 distinct industrial sites.[8] A 70 million United States dollars project to establish a vaccine manufacturing plant within the park led to the establishment of ShieldVax in 2023.[13] Five new and one existing facility achieved national good manufacturing practice compliance, raising the number of compliant sites from zero at the beginning of the national strategy to six.[9] However, major industrial targets remained unmet. No local firm has achieved WHO prequalification, limiting participation in large, donor-funded global health tenders. Domestic active pharmaceutical ingredient manufacturing also remained entirely unfulfilled due to high capital costs, complex chemical processes and energy requirements, leaving manufacturers dependent on imported raw materials.[1,4,10] At the same time, capacity utilization averaged only 43% across the industry largely because foreign currency shortages constrained imports of raw materials and other inputs.[10] Consequently, the local market share via the Ethiopian Pharmaceuticals Supply Service's Revolving Drug Fund procurement stood at 23% in 2024, missing the 60% target.[11]

Implications for patients

Expansion of local production increased the coverage of the National Essential Medicines List produced locally from 90 to 140 chemical entities across 167 dosage forms.[8] A 30% advance payment scheme for domestic firms also helped reduce stockouts risks for commonly used medicines (including antibiotics and analgesics), particularly during periods of global supply disruption.[1,4] Both of these developments have helped create a more consistent supply within public health facilities, which is critical for patients needing timely access to essential treatments. The growth of local manufacturing has also improved the efficiency of medicine procurement and distribution, reducing lead times in some public tenders. Importantly, improved regulatory oversight and manufacturer quality systems have reduced the circulation of substandard or falsified medicines, strengthening patient safety and treatment reliability.[14,15] While these changes may have eased access for patients in certain contexts, broader economic pressures such as inflation and currency fluctuations continued to constrain sustained improvements in affordability.[10] The strategy and related sectoral policies focused largely on supply and

production capacity. There was less emphasis on complementary measures to promote appropriate medicine use, such as programmes to ensure responsible use of antibiotics and improve prescribing practices. Consequently, increased availability has not yet been fully matched by improvements in appropriate use at patient level.

Benchmarking

In September 2025, the Ethiopian Food and Drug Authority achieved WHO Maturity Level 3 for the regulation of medicines and vaccines (non-producing),[14,15] confirming that Ethiopia's regulatory system is stable and functioning. Ethiopia became one of only nine African countries to attain Maturity Level 3 status, strengthening regulatory credibility, mutual recognition among participating authorities, reducing duplication and accelerating access to quality-assured medicines.[14,15] Ethiopia's participation in regional economic frameworks, including the African Continental Free Trade Area and the Common Market for Eastern and Southern Africa, further enhances opportunities for regional market integration.[15]

Lessons learnt

Several lessons were learnt from implementing the national strategy (Box 1). First, dual-chaired governance is essential for policy coherence. The joint steering committee aligned industrial policy, public health priorities, regulatory oversight and public procurement. Sustained political commitment supported cross-sectoral collaboration and implementation.

Second, regulatory credibility is a powerful market enabler. Achieving WHO Maturity Level 3 confirmed that Ethiopia's medicines regulatory system was stable and well-functioning.[15] The milestone strengthened investor confidence, enhanced the credibility of locally manufactured medicines and created opportunities for regional regulatory harmonization.[15]

Third, industrial infrastructure requires adequate market and financial support. Strategic investment in the Kilinto Pharmaceutical Industrial Park, with factory plots, infrastructure and services in place, reduced startup costs and operational barriers. Reforms enabling the centralized public procurement system to meet domestic demand further strengthened the market.[4,9] However, persistent foreign exchange shortages constrained imports of active pharmaceutical ingredients and other inputs, limiting capacity use. Ghana similarly combined a 15% procurement price preference and negative import list with the Export Trade, Agricultural and

Industrial Development Fund to support factory upgrades but continued to face fragmented procurement and WHO prequalification barriers.[5] These experiences demonstrate that infrastructure, market support and access to finance need to operate as complementary policy instruments.

Fourth, upstream supply chain resilience remains a strategic priority. Dependence on imported active pharmaceutical ingredients and production inputs exposes manufacturers to foreign exchange shortages and global supply disruptions. Greater upstream manufacturing, diversified raw-material sources and stronger regional supply networks are key to sector resilience and competitiveness.

Finally, the ultimate measure of success should be patient-centred, with manufacturing capacity, investment and regulatory maturity important intermediate outcomes. Ultimately, local production should improve access to affordable, quality-assured medicines and strengthen health security.

The fact that several targets remained unmet reflects implementation challenges rather than strategic shortcomings. The shortfalls should be interpreted within Ethiopia's broader macroeconomic and global operating environment; they were compounded by the coronavirus disease 2019 pandemic. Implementation was hampered by global supply chain disruptions, foreign currency shortages and the capital-intensive nature of active pharmaceutical ingredient manufacturing. In response, government institutions are strengthening investment promotion, expanding technical assistance for WHO prequalification, improving access to industrial financing, and exploring mechanisms to support upstream pharmaceutical manufacturing and greater export competitiveness. Looking ahead, Ethiopia should consolidate its gains by strengthening pharmaceutical workforce development, promoting selected upstream manufacturing and developing the next national strategy in closer alignment with universal health coverage and pandemic preparedness.

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Competing interests:

None declared.

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Box 1. Summary of main lessons learnt

Aligning industrial, regulatory and procurement policies under clear, cross-sectoral accountability helps convert domestic manufacturing capacity into reliable patient access.

Coupling international regulatory credibility (such as WHO Maturity Level 3) with secured, timely public procurement helps minimize stockouts.

Ensuring access to raw materials and foreign currency for local production helps protect long-term availability and affordability of essential medicines.

WHO: World Health Organization.

Table 1. **Selected indicators of progress and targets of the national strategy and plan of action for pharmaceutical manufacturing development,[4] Ethiopia**

Indicator	2020 mid-term target	2025 end-term) target	Achieved (2025)
No. of new manufacturing companies established	5	11	5[8]
No. of manufacturers with national good manufacturing practice compliance	5	20	6[9]
No. of manufacturers of active pharmaceutical ingredients	1	3	0[10]
No. of WHO prequalified products produced locally	4	15	0
% of essential medicines purchased by the Ethiopian Pharmaceuticals Supply Service from local firms	50	60	23[11,a]
Export of locally produced medicines, in US$ million[b]	30	80	< 2[12]
No. of graduates in industrial pharmacy or regulatory sciences[c]	200	1500	~40

US$: United States dollars; WHO: World Health Organization.

[a] Percentages have been calculated as follows: the total local procurement of medicines by the Ethiopian Pharmaceuticals Supply Service divided by the service's total procurement under its Revolving Drug Fund.

[b] Export values are based on the United Nations Comtrade Database.[12]

[c] Data on graduates in medicines regulatory sciences were compiled from personal communications (2025, 2026) with programme coordinators at the relevant Ethiopian universities.