

Should sub-Saharan Africa make its own drugs?

A comprehensive analysis of the business, economic, and public-health impact finds the potential for local production of pharmaceuticals to be a mixed bag.

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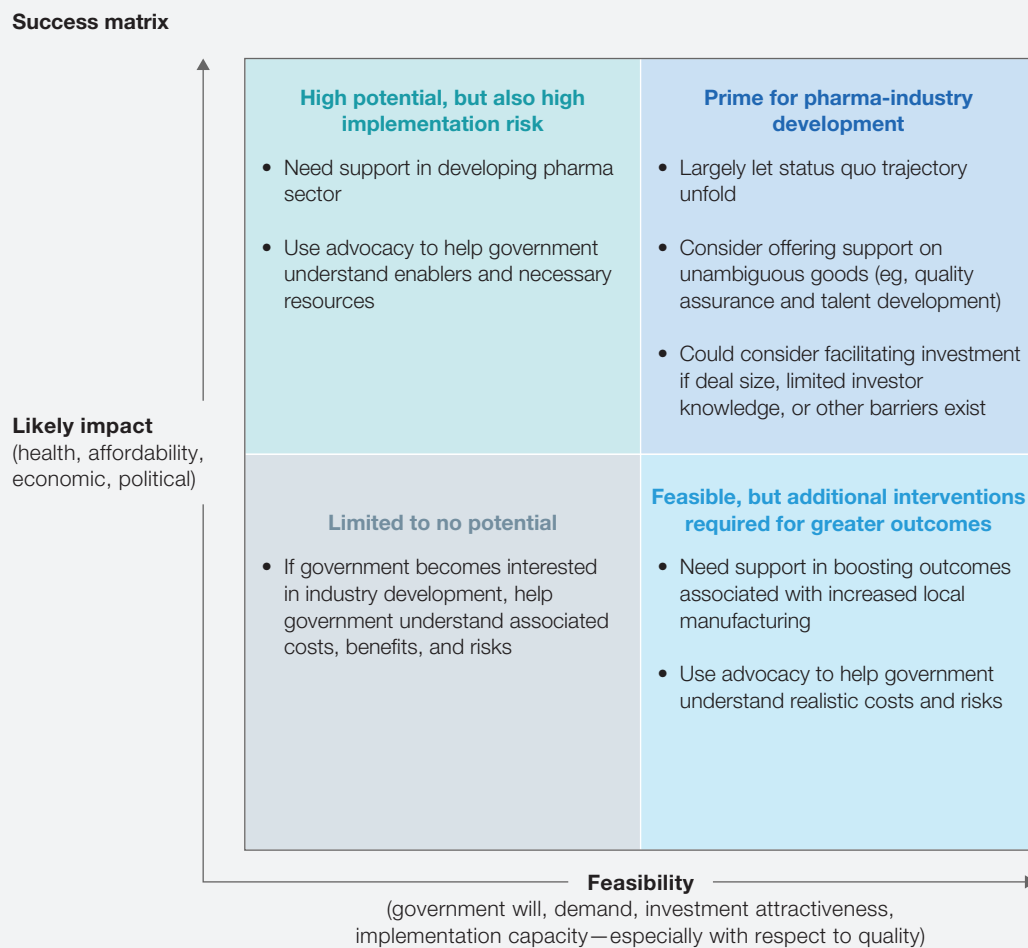


With imports comprising as much as 70 to 90 percent of drugs consumed in most countries in sub-Saharan Africa, many governments are considering whether it's time to promote more local production. Drug imports, including both over-the-counter and prescription drugs, do considerably exceed those into China and India—where comparable populations import around 5 percent and 20 percent, respectively. And it does put strain on government and household budgets and already limited foreign exchanges.

To better understand the realities of promoting local drug production, we undertook a systematic

analysis of the current state of the market. The analysis focused on simple, small molecules, such as generic drugs, since the economics and technical challenges would vary for more complex products, such as combination drugs, injectables, and vaccines. We evaluated the costs and benefits of increasing production not only in economic terms but also in their impact on the wider economy and on public health systems. We then compared that to local measures of feasibility, including government will, demand, investment attractiveness, and implementation capacity, especially with respect to quality (Exhibit 1).

Exhibit 1 Successful efforts to develop local drug manufacturing will depend on both impact and feasibility.



The analysis depicts an opportunity that varies from country to country. In some countries, a manufacturing hub is unlikely to be economical. In a half dozen or so others, such a hub could be viable if it can overcome structural obstacles—a relatively small, if growing, market; a global excess of manufacturing capability for some kinds of drugs; unreliable infrastructure; and an underdeveloped talent base. For those countries, a local industry might make drugs modestly more affordable—an important factor in an area where out-of-pocket drug costs can be a significant impediment for all but the most wealthy consumers.¹ It could also improve public health, enhancing access to drugs at a time when the donor programs that have long provided drugs in some countries are facing flat or declining budgets. Even there, however, the effect of local production on jobs and GDP would likely be minimal relative to the size of these economies overall.

Pharmaceutical production in sub-Saharan Africa lags behind comparable regions

Some African countries have a handful of local companies who produce for the domestic market. Most do not—and are currently uncompetitive for local drug production (Exhibit 2). The continent overall has roughly 375 drug makers, most in North Africa, to serve a population of around 1.3 billion people. Those in sub-Saharan Africa are largely clustered in just nine of 46 countries, and they're mostly small, with operations that do not meet international standards. By comparison, China and India, each with roughly 1.4 billion in population, have as many as 5,000 and 10,500 drug manufacturers, respectively. And the sub-Saharan market's value is still relatively small, at roughly \$14 billion compared with roughly \$120 billion overall in China and \$19 billion in India.²

In sub-Saharan Africa, only Kenya, Nigeria, and South Africa have a relatively sizable industry, with dozens of companies that produce for their local markets and, in some cases, for export to neighboring

countries. Local producers also play in a limited range of the value chain. Almost all of them are drug-product manufacturers—that is, they purchase active pharmaceutical ingredients (APIs) from other manufacturers and formulate them into finished pills, syrups, creams, capsules, and other finished drugs. Up to a hundred manufacturers in sub-Saharan Africa are limited to packaging: purchasing pills and other finished drugs in bulk and repackaging them into consumer-facing packs. Only three—two in South Africa, and one in Ghana—are producing APIs, and none have significant R&D activity.

What's the value of increased local drug production?

Developing a local drug industry in sub-Saharan Africa would take decades of sustained and careful effort. Examining the value of such an undertaking involves more than the economics of individual-company-level business. Because pharmaceutical products have such wide-ranging effects, country governments and citizens often think about the industry's impact in broader economic terms, including economic growth and job creation, and in terms of public health, such as access to medicines and preparedness in the event of disease outbreaks. To examine which dimensions really matter, we disaggregated the notion of impact into affordability, health impact, and economic impact.³

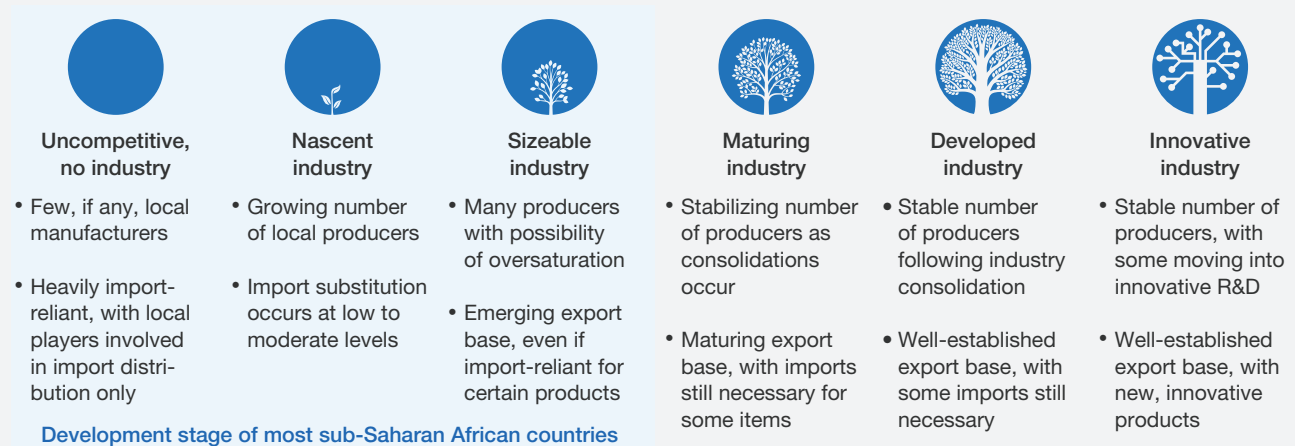
More affordable drugs

We frequently encounter public-health officials and potential investors who argue variously that locally manufactured drugs would be cheaper once all the costs are factored in—as well as others who take it for granted that it's cheaper to produce drugs in India than it would be in Africa. The analysis suggests some truth to both arguments: drugs today are cheaper when imported, but with comparable facilities some drugs tomorrow could be cost competitive or even cheaper than imports from India. This is more likely true of basic oral solids than more advanced and larger-molecule drugs.

Exhibit 2

Most sub-Saharan African countries are at the earliest stages of pharmaceutical-industry development.

Development stages of the pharmaceutical industry



Consider our modeling of comparable plants producing one common over-the-counter drug, for example. We found that when imported, the drug's landed price in Ethiopia consists of the manufacturer's price in India plus a more-than-20-percent markup as a result of freight, duties, and value-added tax (Exhibit 3). If the same drug were manufactured in Ethiopia: the raw materials would still be imported, but the import costs would be lower because of their relatively low value. Adding the local conversion cost due to lower manufacturing efficiency and the producer margin to the total leads to a price that is higher than in India, but the lower transport cost to reach the distributor means that the locally manufactured product is still more affordable at the point of entry into the local supply chain. In fact, for a range of products, including tablets, capsules, and creams, costs for most drugs produced in Ethiopia and Nigeria tend to be about 5 to 15 percent lower than the landed price of imports from India.

For most countries in sub-Saharan Africa today, this is largely a theoretical scenario. With current facilities, costs there today are typically higher

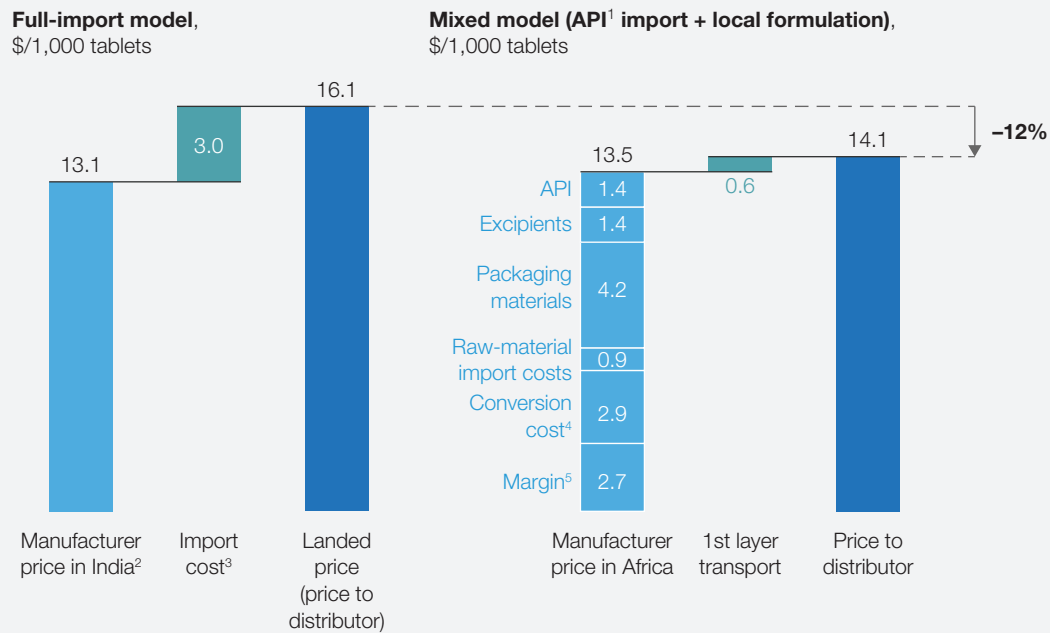
because production facilities generally have less capacity and lower utilization rates than plants in India. Moreover, the affordability of drugs also depends on the structure of local supply chains, which differs between regions. Supply chains in anglophone countries of sub-Saharan Africa are more informal than in francophone countries. Markups and pricing are often unregulated in the former and also feature substantial numbers of informal stores.

Improved public health

Increased pharmaceutical manufacturing can affect a population's health in various ways, such as its access to, awareness of, and availability of needed medicines. It can also impact the systems that regulate quality and safety. These effects will vary country by country because they are influenced heavily by each country's configuration of the health system and health market. Yet our analysis for Ethiopia and Nigeria highlighted some effects that may be applicable for other countries as well.

Access to medicines, for example, is often limited to outdated drugs because global drug originators,

Exhibit 3 When scale and utilization are held constant, local manufacturing can be more cost competitive than imports.



Note: This analysis is for 1 over-the-counter drug in Ethiopia; economics for other drugs may vary.
¹ Active pharmaceutical ingredient. ² Per cleansheet model. ³ Includes freight: 10%; duties: 5%; and value-added tax: 5% of API value. ⁴ Includes direct labor, testing, facility, equipment, and overhead costs. ⁵ Margin for local manufacturers ~20%.

or patent holders, lack incentives to undertake the cumbersome process of registering and promoting all their products for each small African country market. As a result, many African countries still use drugs older than what is recommended by the World Health Organization’s (WHO’s) essential drug list. Local manufacturers often have the incentives and resources to introduce newer generation generics into smaller African markets. In Ethiopia, when one local player became the first in the country to produce a newer-generation antibiotic, the government added it for the first time to the list of products available to public health facilities. In Nigeria, regulations allow local drug manufacturers to also be drug importers. Many of the leading local drug manufacturers are also representatives of global drug originators, and hence have a strong incentive to invest in local drug registration and the

introduction of lucrative new products. That said, few markets in Africa are as potentially lucrative as Nigeria. Therefore, we expect the impact of increased local drug manufacturing in most other countries to more closely resemble the economics in Ethiopia than in Nigeria.

Another arena in which we expect increased local drug production to have positive effects is in the regulation and quality assurance of drugs in local African markets. In Ethiopia, for example, the government’s desire to spur local drug manufacturing has come hand in hand with a commitment to strengthen its national drug regulator, the Food, Medicine, and Health Care Administration and Control Authority. The government has also committed to reducing delays in product registration, ferreting out counterfeit

drugs, and pushing manufacturers to meet standards required for exports. Overall, Ethiopia is investing ahead of the curve in regulatory capacity. Although its pharma market is only valued at approximately \$600 million, its regulator's budget is \$6.6 million, a higher ratio than observed in Brazil, Russia, and Turkey.

Improved economy

Proponents of local drug manufacturing in sub-Saharan Africa often express their argument in economic terms: economic diversification, GDP growth, the impact on the balance of trade, and job creation. However, our analysis suggests that pharmaceuticals would remain a relatively small sector of the overall economy, even assuming significant growth. The effect on annual GDP growth would likely be negligible—on the order of \$190 million per year by 2027 for Ethiopia and \$230 million per year for Nigeria, over a period when we project annual growth for the two countries could be on the order of \$14 billion and \$27 billion, respectively.

The largest effect would be on the balance of trade. If Ethiopia and Nigeria were to increase their local share of production from roughly 15 to 20 percent to around 40 to 45 percent, both countries could expect to see their trade balances improve by \$150 million to \$200 million annually. In Ethiopia, trade imbalances have been a critical issue for several years as the country has dealt with a severe shortage of foreign exchange. A swing of a couple of hundred million dollars in a decade's time would certainly be welcome. But it would be hard to feel, since it amounts to less than 5 percent of Ethiopia's projected foreign currency needs—not including the additional capital investments needed to build industrial parks and upgrade national regulators.

An increase in local production would not create many jobs. Modern pharmaceutical plants employ only a few hundred workers. New entrants tend to be

even leaner: the two new Chinese entrants into the Ethiopian market, for example, are building more automated production facilities and hence employ only around 200 workers on average. Altogether, the total job creation affected by increased local pharmaceutical production is likely to be on the order of a few thousand jobs at best—even including any impact it has on jobs upstream and downstream, in its suppliers and distributors.

Is it feasible?

The feasibility of building an industry in any country is influenced by both private- and public-sector factors. On the private side, the inherent market dynamics, and the attractiveness of available investments, will determine whether there is a strong business case for putting money into the pharmaceutical sector. These include, for example, whether there's enough unmet demand to make a sizeable plant competitive and the practicalities of exporting excess production. On the public side, governments have several potential levers to encourage local production. These include local production incentives in national tenders, subsidies and tax breaks, investment in special economic zones, and talent- and skill-building programs. The availability of these levers varies across countries, and individual governments' attitudes toward the pharmaceutical industry influence their willingness to employ these levers.

Overall, our analysis convinced us that increased local drug production is feasible in about a half dozen sub-Saharan African countries at current and projected demand levels. While only South Africa is currently as attractive to private-sector pharmaceutical investors as Brazil and India, other countries are rapidly improving their investment climate. Each has its own strengths and weaknesses relative to Brazil, China, and India. Some are stronger in areas like logistics, business climate, and tax policies. Others might do well in some areas, such as tax policy, logistics, and technology, but show

weaknesses in government and business climate. Still others could quickly become attractive to international investors with continued improvement.

Creating a sustainable pharma sector in sub-Saharan Africa

In those countries where increased local production of pharmaceuticals would be both feasible and have a positive impact, the question is how to do it. Through our research, we have distilled five lessons that could help them do so in a way that contributes most to the health of their people and the well-being of their economies. These include a focus on quality, production capacity (or scale), regional hubs, drug-product formulation, and value-chain effects.

Focus on quality

Regulatory standards and enforcement across sub-Saharan Africa typically lag behind global standards. There are only six companies operating in the region that have achieved WHO prequalification.⁴ The fight against counterfeit, expired, and substandard drugs is improving, but it is still common in some countries in the region.

As sub-Saharan Africa develops its local pharmaceutical industry, it is imperative that countries continuously upgrade their quality standards and enforcement. Beyond saving lives, a stronger regulatory system would allow for a fair and competitive playing field, eliminating low-priced, substandard products from the market. To do so, country leaders may need to commit to ongoing funding for their regulatory agencies in accordance with established global benchmarks or perhaps consider continent-wide efforts such as those in Europe. This would allow regulators to address some of the existing gaps in training, capabilities, and manpower in regulatory oversight and quality control. Another priority should be cultivating and sustaining a healthy pipeline of regulatory talent, since turnover is brisk for many agencies as trained staff quickly leave for private-sector jobs.

Build plants with sufficient production capacity

Any theoretical production-cost advantages that countries in sub-Saharan Africa might enjoy could be outweighed by their lower production capacity and utilization relative to India. Most production in the region today is in small plants with low capacity—plants need to be big enough and have enough capacity to get the benefits of scale economics. And utilization is affected by unreliable infrastructure, frequent power interruptions, and high logistics costs.

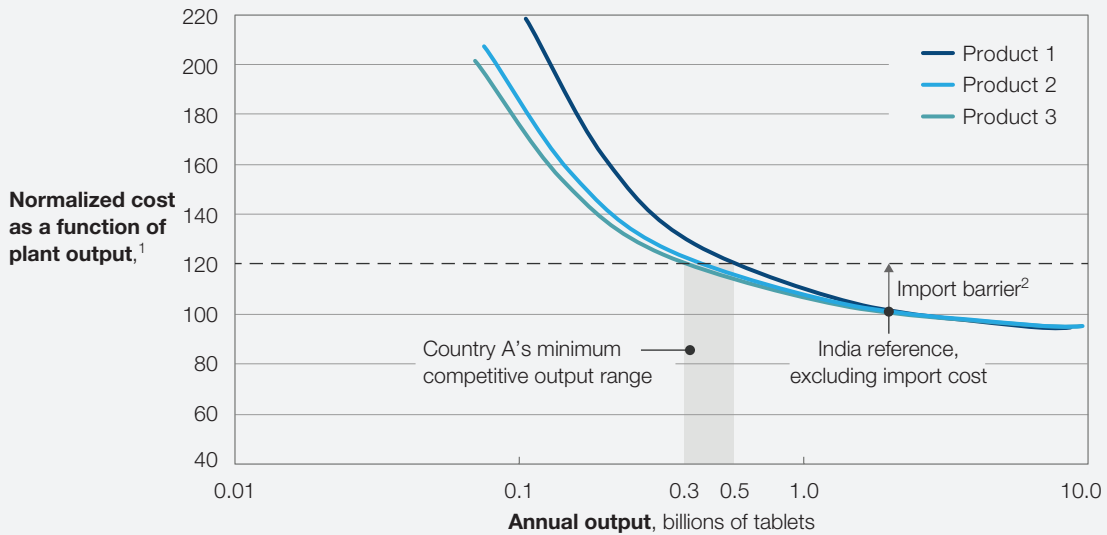
At what point would manufacturing plants there become competitive with imports? According to our analysis, production volume—that is, the plant's capacity times utilization—affects economics and affordability disproportionately more than other commonly cited concerns, such as labor productivity and electricity costs. The cutoff for output depends on product type, but for a tablet-based product it would be around 500 million tablets (Exhibit 4). Smaller plants are unlikely to be competitive with imports, even running at full utilization, and plants operating below the cutoff today may not be sustainable over the long term.

Thus, as old plants get upgraded and new plants get built, companies in sub-Saharan Africa should ensure that they will meet a certain threshold of production while ensuring that there is sufficient market demand to maintain health utilization. Companies should estimate the necessary break point for their specific mix of products and location, and plan their investments accordingly. Country governments might also reconsider incentives to companies that meet competitive levels of production.

Create regional hubs that include smaller countries

Given the minimum production requirements and the fact that there are only a few countries where pharmaceutical manufacturing is feasible, sub-Saharan African countries could work together to encourage a handful of globally competitive industry

Exhibit 4 For tablet-based drugs, pharmaceutical plants in Africa need the capacity to produce roughly half a billion tablets to be cost competitive with India.



¹ Assuming India output of 2 billion tablets. Assumes plants are fully depreciated.

² Import cost is 20%.

Source: Interviews with local manufacturers in Ethiopia and Nigeria; McKinsey analysis

clusters. These clusters have a better chance of producing affordable, high-quality drugs than if efforts were dissipated across a larger number of subscale investment attempts throughout the continent. With proper regulatory harmonization, smaller countries could experience faster lead times and more responsive supply chains because they could be served by local, and not overseas, suppliers.

There is already a broader movement to create freer trade across Africa. The newly established Continental Free Trade Area (CFTA) seeks to bring the 55 members of the African Union together. By spring 2018, 44 states had formally joined CFTA. Predating the CFTA, regional economic communities have also been working on removing tariff and nontariff barriers to trade.

Yet these efforts are not enough to enable the creation of regional hubs for pharmaceuticals, since

drugs are such a highly specialized product. The African Medicines Regulatory Harmonization effort has yielded noteworthy results, with the East Africa Community countries at the stage of conducting joint assessments and inspections. However, it is still not possible for companies to file a single registration that is recognized by neighboring countries anywhere in sub-Saharan Africa today. Until that happens, no at-scale company can realistically serve multiple countries.

Focus on drug-product formulation, but keep an eye on new technology

Focusing on the right part of the value chain will be critical to the success of a pharma sector in sub-Saharan Africa. APIs today are very scale sensitive and hard to manufacture. Most countries in the region lack the requisite chemicals sector for API production, which our modeling suggests would already be 10 to 15 percent costlier than imports

from India. That makes drug-product formulation the better bet, while continuing to import APIs—for now, at least.

Looking ahead, this focus could evolve. New technologies could lower API costs—whether by changing the scale economics needed to keep prices competitive, making manufacturing easier, or improving quality. Indeed, one advantage that sub-Saharan Africa has is the opportunity to adopt cutting-edge technologies without worrying about replacing existing technologies in legacy plants. Some of the most promising technologies on the horizon include improved process chemistry, continuous manufacturing, and modular plant design. Using Ethiopia as an example, employing improved chemical-synthesis processes could reduce costs by approximately 5 to 35 percent, and continuous production could cut costs by another 10 to 25 percent, if the right molecules are chosen for production. In addition, modular plant design could speed construction of these plants and ensure tighter quality assurance.

Upgrade the value chain

Though the focus may be on drug-product manufacturing, countries might also consider upgrading the value chain beyond just manufacturers. Many countries in sub-Saharan Africa have a highly fragmented landscape of distributors, wholesalers, and retailers, who all add their individual markups to the product. In some countries, for example, it's not unheard of for a drug to be marked up by nearly double the manufacturer's price by the time it reaches the end consumer. In addition to raising the price of drugs, this system also has the effect of compromising quality assurance, since each additional step creates the potential for improper storage, tampering, or delay, even as drugs near their expiration dates.

To get the value chain under control, governments might better enforce quality standards in distribution, wholesaling, and retailing, for example. Many tiny unregulated shops today don't meet standards already on the books. If they did, it may encourage some industry consolidation and encouraging discipline that will also lead to better patient outcomes.



There are some who have questioned the ability of the countries in sub-Saharan Africa to build a local pharmaceuticals industry, and others who question the wisdom of doing so. To those skeptics, the analyses presented here should provide comfort that the potential for building a robust local industry could be real in some countries under the right conditions. It is now for public- and private-sector leaders in the region to decide whether to try. ■

¹ Tania Holt, Laura Millroy, and Matthews Mmopi, "Winning in Nigeria: Pharma's next frontier," May 2017, McKinsey.com.

² Figures are from 2017. Sources for sub-Saharan Africa: BMI, McKinsey analysis. Sources for China: AESGP, Fitch Solutions, local news sources, NBS, SMEI, Wind Financial Terminal. Sources for India: AIOCD-AWACS, Fitch Solutions, local news sources, OPPI.

³ We also considered political impact, but it is difficult to quantify and will vary from country to country.

⁴ As of February 2018.

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