Africa: A ripe opportunity
Understanding the pharmaceutical market opportunity and developing sustainable business models in Africa
As growth opportunities continue to move away from the traditional pharmaceutical markets, most multinationals have Africa in the sights of their expanding global footprint. It is a continent ripe with potential, but the challenges for developing a viable market strategy are formidable. Understanding the dynamics and underlying demographics will be key to ensuring a sustainable business model for the future.

IMS Health has conducted a study combining IMS intelligence with secondary research and primary interviews with the pharmaceutical industry, international and African organizations. The study explores critical questions that companies are asking in entering or optimizing their presence in Africa: Why is investing strategically important? Where are the major opportunities? And what will it take to be successful in this fast-evolving region?

AFRICA WILL BE A SIGNIFICANT ECONOMIC FORCE IN THE FUTURE AND PHARMACEUTICAL COMPANIES HAVE MUCH TO GAIN

By 2016, pharmaceutical spending in Africa is expected to reach US$30 billion. This value is driven by a 10.6% compound annual growth rate (CAGR) through 2016, second only to Asia Pacific (12.5%) and in line with Latin America (10.5%) during this period. Spurred by a convergence of demographic changes, increased wealth and healthcare investment, and rising demand for drugs to treat chronic diseases, this market potentially represents a US$45 billion opportunity by 2020.

The pharmaceutical growth is a reflection of economic strength accompanied by increasing healthcare spending. Sub-Saharan Africa (SSA), excluding South Africa, is notable in this regard: according to the Economist Intelligence Unit, its economies are growing faster than anywhere else in the world and this trend is expected to continue. Underpinning these prospects are a series of positive economic trends: greater political and fiscal stability and improvements in pro-business legislation have led the United Nations (UN) to forecast that Foreign Direct Investment (FDI) in Africa could more than double by 2014, despite speculative money leaving the continent following the collapse of Lehman Brothers, and the Arab Spring restricting investment in North Africa. This FDI is fuelling macroeconomic growth and vastly improving access to new technology. The recent boom in mobile subscribers reflects this trend: as of mid-2012, there were more than 600 million mobile subscribers on the continent, surpassing American and European figures. At the same time, major demographic shifts show an increasing number of working-age Africans, a rising middle class which accounts for 34% of the continent’s inhabitants, and an urban population expected to exceed that of China’s and India’s by 2050.

Alongside the increasing economic wealth is a notable rise in healthcare spending, which has grown at a CAGR of 9.6% since 2000 (across 49 African countries). Fuelled by government, non-government organizations (NGOs) and private sector investment, this has largely focused on strengthening health system infrastructure, capacity building, treatment provision and specialized services.
Real gross domestic product (GDP) is expected to grow at 5% per annum through 2017 in SSA and this trend of rising healthcare spending is expected to continue.6

The changing economic profile of Africa is also linked to an increased demand for chronic care drugs, reflecting a marked shift in the burden of illness towards non-communicable diseases (NCDs) and the continued impact of human-immunodeficiency virus and acquired immune deficiency syndrome (HIV/AIDS) on the continent. The NCD proportional contribution to the healthcare burden is forecast to rise by 21% through 2030.7 While continuing to struggle with infectious and parasitic illnesses, Africa is expected to experience the largest increase in death rates from cardiovascular (CV) disease, cancer, respiratory disease and diabetes over the next ten years, resulting in greater demand for healthcare services and appropriate medicines.

The combination of economic strength and an expanding middle class is already driving a demand for medicines across Africa. For example, in Algeria, Morocco and Tunisia, a rise in wealth has triggered demand for chronic medicine consumption (Figure 1). In Algeria, the chronic medicine to essential medicine ratio increased by 72% from 2002 to 2011, accompanied by a total Gross National Income (GNI) increase of 70%.8,9,10 A similar trend is likely to emerge in other countries, such as Kenya and Botswana, where NCDs have been declared a national priority at the ministerial level.

**FIGURE 1:** SELECT MARKETS EXEMPLIFY A RISE IN WEALTH ALONGSIDE GREATER CHRONIC MEDICINE CONSUMPTION

Source: IMS Health MIDAS, June 2012. African countries coverage only includes retail panels. Gross National Income per capita (PPP) from the World Bank World Development Indicators database. Essential molecules were defined by the WHO Model List (revised March 2009; 16th edition).
Notwithstanding its growth potential, Africa presents a complex, multifaceted set of markets, which are highly heterogeneous in terms of pharmaceutical growth, language and trading blocs (Figure 2). Consequently, the opportunities they offer are also quite variable. Understanding the nuances and navigating the challenges are key to establishing successful and sustainable operations.

To date, three types of pharmaceutical industry players have a track record of success, defined as sustainable revenue-generating business operation: innovative multinational companies (MNCs), Indian and Chinese pharmaceutical companies, and local manufacturers in Northern and South Africa.

1. MNCs
Most of the major pharmaceutical MNCs have had a presence in Africa for a number of years. Among the first companies (or precursors of today’s companies) to enter the continent were Abbott (South Africa, 1930s), Sanofi-Aventis (Morocco, 1953), Novartis (Egypt, 1962), Pfizer (Morocco, 1963) and GSK (Nigeria, 1971).

MNCs have predominantly focused on, and succeeded in marketing, branded innovative and generics drugs to the private sector in urban areas. Products have typically targeted in-demand therapy areas, such as vaccines, anti-infectives and anti-diabetics, with sales mainly concentrated in Northern and South Africa. Few opportunities have been realized in the public sector although MNCs have had some success through tendering, particularly in the more established markets such as South Africa.
In general, success strongly correlates with linguistic and economic links, where existing business ties stem from colonial history. French companies, for example, have typically performed best in predominantly Francophone North and West Africa, while companies from the UK and former British colonies see the healthiest revenues in predominantly Anglophone East and Southern Africa.

Sanofi is the most successful MNC in Africa to date and the only major top 10 pharmaceutical company to explicitly report its sales in the African continent. Over the course of the last 40 years, the company has demonstrated a firm commitment to the continent, with strong emphasis on decentralized management and increasing local manufacturing. Dominant in the French-speaking nations of West and North Africa, Sanofi has built its success on three areas of focus: emphasis on major population centers and cities, the establishment of longstanding business relationships with the French West African nations, and a broad portfolio spanning multiple therapy areas (both noncommunicable and communicable) with a high degree of relevance in the countries. As the company has emphasized in reporting on its activities in Africa, “Sanofi is a real partner, working hand in hand with health authorities and healthcare professionals to ensure that the right solutions reach those most in need.” This strategy has seen Sanofi post double-digit growth in Africa for the last ten years, reaching MAT sales of US$1.29 billion in Q2 2012.12

2. Indian and Chinese pharmaceutical companies
The expanding presence of Asian manufacturers in Africa has seen the proportion of pharmaceuticals being imported from India and China more than double in value terms in recent years. According to global import and export data, India accounted for 17.7% of African pharmaceutical imports in 2011 (up from 8.5% in 2002) and China for 4.1% (up from around 2.0% in 2002).13

Indian and Chinese manufacturers have gained market share primarily through competitive prices and simultaneously targeting different markets in the generics space. These manufacturers differ across five areas: mode of entry, countries, use of local talent, target payers and brand image. Chinese firms succeed in markets with low ease of doing business ratings, where they sell or gift medicines such as anti-malarials to governments through procurement contracts. Typically, Chinese companies build health infrastructure with funds from the government which come from loans secured against resource extraction, common in countries such as Zambia and Angola. For example, in Zambia, where Chinese companies run some of the country’s copper mines, the Jiangsu International Economic Technical Cooperation Corporation, a construction company that also sells pharmaceuticals and nutritional products, built the Lusaka General Hospital with a grant from the Chinese government. The hospital was then supplied with Chinese-made medical devices and pharmaceuticals, presumably from the same company. In such local operations, Chinese manufacturers have a weak record on skills transfer and local capacity building relative to their Indian counterparts and a poor reputation for medicine quality.17
In contrast, Indian manufacturers primarily sell medicines through NGOs and government tenders in regulated markets. For example, leading Indian players, such as Cipla, Ranbaxy, the Serum Institute and Dr Reddy’s, have strong market presence, particularly in East Africa. In these predominantly Anglophone markets, Indian companies have a reputation for integrating local talent into their operations and are known for the quality of their medicines, with many having achieved World Health Organization (WHO) pre-qualification. While they are best known for selling affordable HIV medicines in Africa, they are rapidly broadening their medicine range across therapy areas.

3. Local industry
The success of local pharmaceutical companies is frequently contingent on their ability to attract MNCs into research and development (R&D) licensing arrangements, a strategy which endorses their production capabilities. Local companies in South and Northern Africa have been leaders in their domestic markets. For example, Aspen (South Africa), Adcock Ingram (South Africa), EIPICO (Egypt), Sailed (Algeria) and Cipla Medpro (South Africa) have combined licensed originator brands and their own branded generic products. Aspen is now Africa’s largest domestic pharmaceutical company with a strong reputation for quality products. Aspen’s maturity in the domestic market resulted from a strong partnership with GSK which included product licensing arrangements as well as skills and equity transfer. Cipla Medpro, a local company in South Africa, is the third largest pharmaceutical company in South Africa by value and is expanding to Botswana and Namibia.

While success stories of local industry players exist, the majority have struggled to compete for two reasons. Firstly, the high costs of active pharmaceutical ingredients (APIs) in Africa has left most unable to compete on price with Asian generic manufacturers and unable to access the most in-demand therapy areas. Secondly, domestic manufacturers have struggled to implement good manufacturing practices (GMP) and ensure quality production. As a result, few companies have WHO pre-qualification status. For this reason, NGOs, which have historically been prime procurers of medicines on the continent, have refused to buy essential medicines (e.g., anti-infectives) from domestic manufacturers. Additionally, poor GMPs have been barriers for the International Finance Corporation (IFC), part of the World Bank Group, in its search to identify viable investment opportunities in the domestic industry market.

Nevertheless, MNCs and the WHO are now working with local players to help them obtain WHO pre-qualification. For example, the WHO and UNITAID have been offering capacity building and technical assistance to local Nigerian drugmakers that has also resulted in progress towards achieving GMP standards and pre-qualification.

Pharmaceutical companies need to understand the similarities and differences across the continent that hinge on geographic, economic and cultural attributes.
COMPANIES MUST ACKNOWLEDGE THE SIMILARITIES AND DIFFERENCES IN MARKET OPTIMIZATION STRATEGIES RELATIVE TO OTHER WESTERN AND EMERGING MARKETS

The key elements underpinning a successful market strategy in Africa are similar to those elsewhere in the world: choice of location, operational strategy and portfolio selection. When selecting target markets, a consideration for economic strength, the adequacy of the healthcare environment, demographic transitions towards a larger population of working age, and therapy potential are critical. From an operational perspective, both market entry and optimization strategies should align with company commitment, consider a decentralized decision-making approach and strategically engage key stakeholders. Operationally, an entry and/or expansion strategy will include consideration for the degree of local investment from manufacturing to licensing. Market characteristics, such as disease burden and ability to pay across public and private payers, should be assessed in determining product portfolio.

However, there are three differentiating attributes to Africa when it comes to assessing what it takes to succeed. Firstly, to really fulfill pharmaceutical opportunity potential, a strategy needs to be tailored for different areas within a large, heterogeneous market. Pharmaceutical companies need to understand the similarities and differences across the continent that hinge on geographic, economic and cultural attributes. Secondly, unlike Western and other pharmerging markets, most African markets have nascent market access capabilities. This is predominantly manifested in the hurdles companies must overcome when registering, pricing and distributing their product (e.g., path to market) and in ensuring their product is accessible and usable by the patient (e.g., path to patient). Finally, African markets are still poorly understood: information on medicine consumption is not systematically collected, resulting in fragmented and patchy data. Consequently, market players need to work with local partners to strengthen and leverage data collection to inform the opportunity. Information is also crucial to sustain and build the opportunity moving forward, just as robust data has become a cornerstone of care provision and quality improvements in traditional markets.

Acknowledging these differentiating attributes, companies can harness the opportunity by making strategic choices on location, operations and portfolio.

Location: General market attractiveness can be assessed across geographic tiers, taking into account existing hurdles in the path to market and path to patient.

Pharmaceutical companies should assess general market attractiveness across different geographic tiers. For new and existing market players, location is the first strategic consideration. All geographic assessments will include general determinants of attractiveness, including economic and healthcare strength, demographics and therapy potential. However, Africa’s one billion lives are scattered across geographies defined by regions, countries and cities. Moreover, where to play in Africa is also influenced by varied levels of development along the path to market and path to patient.

African markets are still poorly understood: information on medicine consumption is not systematically collected, resulting in fragmented and patchy data.
Path to market is the process a company goes through to bring its product to the point of dispensing. Path to patient is the route a patient follows from onset of illness to receipt of treatment. Ease of market entry and patient accessibility to medicines differ considerably across countries, and there is further variation between the public and private sectors. Understanding these dynamics across geographic tiers in Africa is essential.

An assessment of regional diversity by linguistic, cultural and trade-related attributes can inform a regional strategy. Commonalities across these attributes incur benefits from easier transport and movement of goods and people. For example, French West Africa is mainly Francophone with eight former French colonial territories. French West Africa also has a shared currency that is benchmarked against the Euro for ease of trade and currency stability. Northern African countries are predominantly Arabic-speaking and Muslim while Southern African countries are mostly English-speaking. The existence of trading blocs, such as the East African Community (EAC), Economic Community of West African States (ECOWAS), the Southern African Development Community (SADC) and the Common Market for Eastern & Southern Africa/East African Community (COMESA), offer an increasingly attractive market opportunity characterized by the removal of trade tariffs and a move towards harmonized medicine registration processes.

EAC is the most mature trading bloc of the four with the highest sales growth compared to other regions on the continent. The EAC has demonstrated commitment to harmonize medicine access, bolstered by support from the Global Medicines Regulatory Harmonization Multi-Donor Trust Fund (GMRH MDTF) which is financed by the World Bank and the Bill and Melinda Gates Foundation. In 2011, EAC was the first regional economic community to receive funds with the goal of promoting and implementing regional harmonization among six National Medicine Regulatory Agencies (NMRAs) in the region. This three-year project will result in harmonized medicine registration, inspection standards, and information and quality management systems. As the EAC project progresses, this will provide a significant opportunity: spurred by an estimated CAGR of 12.4% over the next five years, this region is anticipated to generate pharmaceutical sales of $5.3 billion by 2016, up from $3.0 billion in 2011.

At the country level, there are four established markets in Northern and Southern Africa which together represent more than half of 2011 pharmaceutical sales in the continent: South Africa, Egypt, Algeria and Morocco. Recent growth in these countries can be attributed to a number of factors but largely reflects an upsurge in health system investment. In South Africa, for example, health system strengthening and an increase in the treatment of chronic diseases are key drivers. Algeria is reaping the economic benefits of escalating oil prices and a government commitment to improve human development through public health policies, infrastructure and education.
Additionally, there are several rising economies in SSA with strong historic and forecasted pharmaceutical market growth. Among the fastest growing of these are Nigeria, Kenya and Botswana (Figure 3).

**FIGURE 3:** IN ADDITION TO ESTABLISHED PHARMACEUTICAL MARKETS IN THE NORTHERN AND SOUTH PARTS OF AFRICA, THERE ARE RISING STARS IN SSA

In the West, Nigeria is the most populous country on the continent with ~160 million people and has enjoyed above average GDP growth for Africa since 2006. The country’s pharmaceutical spending has been rising at a 16% CAGR and this is expected to continue at a slightly lower rate of 13% through 2016. In 2008, the government launched the growing National Health Insurance Scheme as part of a commitment to ensure universal health coverage by 2015. Despite this positive step, there is still a considerable amount of effort needed to cover the intended population. While the goal is to cover the entire population through government revenues and tax contributions, current coverage is merely 6% of the population. Additionally, while HIV and malaria are the leading causes of death, NCDs are rapidly emerging as major public health challenges, particularly in the urban slums which include over half of Nigeria’s population.

In the East, Kenya has committed to spending 15% of its national budget on healthcare amid plans to transform itself into a middle income nation by 2030. With public-private partnerships (PPPs) shaping the healthcare market and membership of the EAC trading bloc reducing regulatory hurdles to entry, Kenya is forecast to have a CAGR of 17% through 2016. This reflects opportunities in both communicable diseases, such as malaria and HIV, and NCDs which are a growing challenge in the country. The rapid increase in diabetes, for example, has seen the launch of a major diabetes treatment and management pilot project sponsored by Novo Nordisk, as Kenya works to “strengthen [their health] systems to face this new threat of noncommunicable diseases.”
In the South, despite Botswana’s small population of 2 million, it has had strong economic growth, political stability and consistent investment in health service infrastructure. This reflects the national commitment to healthcare: public funds represent 80% of expenditure in this area, with tenders valuing and considering quality, not just price. While HIV/AIDS continues to impose a significant burden, rising needs in hypertension, diabetes and cancer will contribute to a doubling in the value of this market to $100 million by 2016. NCDs, along with women’s health issues, have already been singled out as the next key focus of the highly successful Botswana-UPenn Partnership (BUP), originally established to help stem the tide of AIDS.

Other countries across SSA are also coming to the fore, such as Ghana, Mozambique, Ethiopia, Angola and Zambia. Strong pharmaceutical sales growth is expected across these countries in line with rapid growth in GDP.

Country-specific considerations include the benefits of multiple high-growth cities, ability to target a large population and existing market access processes such as registration, pricing and reimbursement. However, countries are not without challenges: income inequality and varied infrastructure strength between urban and rural settings imply that companies must carefully assess their target population and the existing infrastructure in place to reach it.

Between 20-30% or $6-9 billion of Africa’s $30 billion opportunity in 2016 will be driven by the top 10 cities in the continent, defined by the percent of total country spend on pharmaceuticals (Figure 4). According to a report by McKinsey and Company in 2011 on global cities, Africa’s urban centers will be responsible for around 69% of the continent’s growth between 2007 and 2025.

**FIGURE 4:** BETWEEN 20-30% OR $6-9 BILLION OF AFRICA’S $30 BILLION OPPORTUNITY IN 2016 WILL BE DRIVEN BY THE TOP 10 CITIES

A deep dive into individual cities reveals drivers of attractiveness: wealth concentration alongside indicators of human development. For example, in Nigeria, Lagos contributed 8% of Nigeria’s overall GDP in 2011. A similar trend is apparent in Morocco, where Casablanca accounts for nearly 10% of the country’s GDP, and in Uganda, where the capital and largest city Kampala represents about 12% of the country’s GDP. According to research on 25 African cities from the Economist Intelligence Unit, citizens in cities spend 94.4% more, per capita, than their countrymen as a whole.\textsuperscript{29} Human development-related indicators show similar disparities: more than 87% of the adult population is literate in Lagos versus 72% across Nigeria as a whole and the youth literacy rate is even higher at 96.5% compared to less than 85.6% across the country.\textsuperscript{30} In Uganda, the literacy rate in the population aged 10 and over is 92% in Kampala versus 73% in Uganda as a whole.\textsuperscript{31}

Excluding Northern and South Africa, ten major SSA cities make up ~12% of the $30 Billion opportunity in 2016 (Figure 5).\textsuperscript{32,33} These include Luanda, Kinshasa, Khartoum, Dar es Salaam and Harare, all of which represent a high concentration of pharmaceutical spending and many of which will have a future growth rate (beyond 2016) that is likely to exceed that of the top ten cities. Luanda, for example, accounts for 26% of Angola’s GDP and is likely to remain the focal point of growth in this country – a point underscored by RTT Health Sciences, a pharmaceutical supply chain service provider: “When you look at going into Angola you really only need to consider Luanda and possibly Huambo and Lobito.” The importance of African cities has been more recently emphasized in research conducted by the Economist Intelligence Unit on the 25 top African cities, finding that companies across most sectors are late in harnessing the potential of urban centers across the continent.\textsuperscript{34,35}

\textbf{FIGURE 5: EXCLUDING NORTHERN AND SOUTH AFRICA, TEN MAJOR SSA CITIES MAKE UP ~12% OF THE $30 BILLION OPPORTUNITY IN 2016}

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\caption{Pharmaceutical opportunity in 2016 by city excluding South and Northern Africa}
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With comparable economic profiles to other dynamic pharmerging cities, the economic potential and health outcome improvements in some of these urban centers surpasses and will continue to surpass that of countries in which they are situated. For example, whilst being located in an economically weaker country, Khartoum will be comparable to cities in stronger economies like Casablanca and Lagos by 2020, based on forecasted consumption trends. This is because Khartoum’s wealth is concentrated by the geographic proximity of oil refineries and a thriving food processing, textile and glass manufacturing industry.

There are obvious short-term benefits to cities: a concentrated wealthy and educated population, and stronger health system infrastructure and distribution channels. However, long-term sustainability will necessitate consideration for other parts of the country. As countries gain economic strength, the urban versus rural divide is expected to reduce and other locations, including rural areas, will be increasingly important.36

**Existing hurdles in the path to market and path to patient help inform location assessment.** Across all geographic tiers, companies seeking a sustainable business must assess the existing capabilities across the path to market and path to patient (Figure 6).

Hurdles across both pathways will make some markets less attractive than others because they will determine the level of investment companies will need to make to overcome them. Weak regulatory mechanisms and prevalent poverty are the primary drivers of these hurdles and are more pronounced in Africa relative to other parts of the world. Opportunities are greater in countries with minimized hurdles along these pathways.

**FIGURE 6:** GREATER OPPORTUNITIES ARE LIKELY IN COUNTRIES WITH WELL-DEVELOPED PATHS TO MARKET AND PATIENT

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<th>PATH TO MARKET</th>
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<td>Registration Process</td>
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Variation in development exists between public and private markets

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<th>PATH TO PATIENT</th>
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Limited variation between public and private markets

Source: IMS Consulting Group analysis
Hurdles in the path to market exist at every stage in the process and differ between public and private payer channels.

- **Registration process:** Common to both payer channels are the lack of available dossier standards and poor delineation of decision makers, leading to lengthy and often very disparate timeframes for registration. Regulations for registering a drug across SSA, for example, vary significantly but in some cases are time consuming, opaque and open to corruption. These variations are endemic: according to interviews, in Rwanda it can take only 2 weeks to register a product; in South Africa, 3-4 years. Weak regulations and their enforcement increase both costs and risk for MNCs.

- **Pricing & reimbursement:** Within the public sector, barriers include non-transparent tendering and procurement processes, the absence of pricing strategy, limited opportunity for reimbursement and lack of tiered pricing levels. In the private market, companies face the challenge of fragmented payer channels between donors, private insurers and employers, as well high out-of-pocket expenditure imposing access limitations.

- **Distribution:** Inadequate regulatory oversight, risking the entry of substandard and counterfeit medicines, as well as weak infrastructure in cold chain, ordering and transport can be key challenges for distribution in the public sector. Lack of expertise in stock management, poor education and irregular energy supply are major contributors. Challenges in the private sector include fragmented wholesaler and distributor channels, expensive credit and variable quality among local distributors.

- **Marketing & sales:** Efforts to reach out to the public market can be hindered by limited knowledge among physicians regarding disease states and medicine needs. This is due to weak education and insufficient numbers of pharmacies and clinics to distribute medicines to those who need them. Barriers to marketing in the private sector include limited business experience among staff and talent retention among staff. Additionally, specialized and innovative medicines may be challenging to promote due to inadequate knowledge of the related disease among sales staff and physicians.

- **Pharmacovigilance:** Although some MNCs conduct their own pharmacovigilance surveillance in Africa, much of the data is not centralized or examined at the national level. In reality, governments have limited to no means of monitoring medicine use in a target population or sufficient human resources and informatics capabilities at clinics. Clinicians in turn are unfamiliar with the practice and wary of admitting liability. The private market also lacks treatment guidelines and/or the incentives to adhere to them.

*Weak regulatory mechanisms are more pronounced in Africa relative to other parts of the world.*
Hurdles in the path to patient are similar across public and private paying channels, hindering appropriate medicine access and usage.

- **Patient awareness:** Health illiteracy drives low disease awareness in many African countries. Recognition of NCD symptoms is particularly poor. More importantly, individuals are often skeptical or suspicious about modern medicines and their benefits due to misinformation, reflected in low treatment uptake and adherence.

- **Healthcare access:** Access is hindered at the financing and provision levels. A reliance on high out-of-pocket spending for healthcare combined with poverty mean that many patients cannot afford to access healthcare services. Limited and weak health system infrastructure and poorly trained medical personnel exacerbate the challenge. For example, many African countries suffer from an acute shortage of doctors: Mozambique has less than 1 physician per 10,000 population, as do Gambia, Ghana and Ethiopia. As a contrast, South Africa has 7.7 physicians per 10,000.37

- **Diagnosis:** Limited numbers of technically trained staff and poor knowledge of diagnostic procedures among health professionals equate to low levels of diagnosis in many cases. Even individuals who are trained may not have access to the required diagnostic tools. Furthermore, many patients who are often unable to access healthcare services for an appropriate diagnosis will purchase medicine from pharmacies without a prescription or not receive any treatment at all.

- **Treatment:** Inadequate clinician awareness of available treatment options and their appropriate use can prevent patients from accessing medicines. This situation is compounded by a poor understanding of medicine consumption trends which makes it difficult to track adherence and appropriate use. Weak distribution systems add further challenges by driving drug shortages and increasing risk of counterfeit and/or substandard medicine entering the system. Finally, lack of resources implies that follow-up consultations and patient monitoring are a challenge to ensuring appropriate medicine use.

Importantly, the hurdles in the path to patient vary significantly between regions, countries and even cities. While seemingly insurmountable, companies can identify innovative ways to overcome them and ensure a sustainable business. Operational strategy and portfolio selection are over-arching considerations in understanding how to do so.

**Operational strategy: Company commitment, a decentralized decision-making structure and strategic stakeholder engagement are necessary for successful operations.**

For all companies, particularly MNCs, sustainable operations in African countries demand first and foremost company commitment from global or central headquarters to support a viable business. Commitment requires:

- **Clear statement of corporate intent** with explicit and validated goals and realistic expectations and timings for results.

- **Financial support** that helps realize defined goals and targets set for the business recognizing that returns will not necessarily be achieved in the short term.

- **Acceptance of a different approach** that recognizes the unique challenges and complexities of Africa. Ultimately, success is contingent on a business model that is prepared to overcome hurdles in the path to market and patient.
While there are many ways to physically operate in Africa which are similar to other markets, there are challenges which need to be considered. For example, operation-specific options can vary from high local investment such as setting up a subsidiary, manufacturing locally or acquiring, to low local engagement such as partnerships and licensing. Higher levels of investment allow companies to retain maximum control over operations. Acquisitions can also enhance a company’s understanding of the local market. However, Africa-specific challenges to such engagements are significant. These include recruiting and retaining talent, battling unfavorable regulations for foreign companies and ensuring that GMP is maintained, particularly in the presence of unstable power supplies.

Operations characterized by low levels of local investment include partnerships and licensing arrangements. Because they necessitate less presence on the ground, they are more favorable to MNCs. For example, Novo Nordisk partners with Saidal in Algeria to produce insulin through technology and knowledge transfer. GSK has won a number of local manufacturer-directed government tenders by applying through local partners. Nevertheless, challenges include identifying a trustworthy partner and ensuring enforcement of contracted agreements. Additionally, partnerships may be restricted by price sensitivity and mistrust among potential partners, particularly NGOs.

Regardless of the operational model, pharmaceutical companies may choose to retain decision-making power centrally or delegate all or some elements to the regional or local level. A decentralized decision-making structure is most illustrative of long-term commitment to the continent. However, examples exist across the spectrum. At BMS, for example, the key decision makers are global HQ with product uptake outsourced to local agents or licensed out to other companies. At BMS, Africa and other emerging markets are not considered investment priorities due to limited opportunities for high-value biologics. At AstraZeneca, decision-making authority and performance accountability reside at the regional level, while finance and regulatory affairs remain headquarter centralized functions. In contrast, GSK, affirming its strong, long-term commitment to Africa, has almost entirely decentralized decision-making activities, creating multiple autonomous business units across the continent with direct responsibility for their own budgets and performance.
Successful decentralized decision-making activities are human resource intensive and as such work best with a hybrid talent pool that combines the expertise between foreign and local staff. For example, technical expertise of foreign staff in dossier development and marketing can complement the in-market knowledge of local workers who can advise on overcoming regulatory and access hurdles. Local workers can also help build and manage local stakeholders as well as facilitate relationships with key opinion leaders (KOLs). Increased accountability at the local level is important to drive a sense of ownership. This fosters innovation in markets that require a flexible approach on the ground and creates the basis for sustainable business operations over time.

Lastly, successful operations require an assessment of strategic stakeholders who can help the company achieve business objectives in Africa. Influential stakeholders in Africa differ considerably from those in traditional markets at national, regional and local levels. Nationally, for example, NGOs represent patient groups and can be powerful allies in market access decisions. At the regional level, religious groups have tremendous influence with different consumer and patient groups. Outreach to some rural communities would be impossible without the support and cooperation of religious groups and their established infrastructure.

Given the lack of doctors and trained nurses, especially in rural areas, community health workers and pharmacists may be the most relevant professionals involved in prescribing and dispensing medicines. They can be essential to efforts targeting patient education and uptake of medicines. Finally, given the high out-of-pocket spending in Africa, individual preferences and choices are critical. Companies need to find innovative ways to gain trust among patients and people who are most credible with patient groups. In some parts of the continent, the influence of tribal leaders can be paramount.

Strategic partnerships with locally-trusted stakeholders can help companies navigate non-transparent elements of the market access process. In doing so, they allow companies to leverage proven channels to enter the market and reach target patient groups to optimize the go-to-market strategy. Collaboration with public sector payers such as the government, partnerships with NGOs and patient groups can help determine tender requirements and/or opportunities to shape them, as well as identify clinical KOLs who influence guideline development and care for particular patients. Among private payers, distributors and community health workers can support assessments of relevant payer channels and patient preferences to define tactics for building brand loyalty.

Partnerships reduce risk in business operations, thus increasing sustainability of the venture. The caveat here is that any partnership can only be as good as the partner; the challenge is in establishing who is reliable and reputable.

Collaboration with public sector payers such as the government, partnerships with NGOs and patient groups can help determine tender requirements and/or opportunities to shape them.
Portfolio selection: A successful portfolio will be well positioned for the public and private sector, leveraging safety and brand loyalty.

There are two dynamics in Africa that influence portfolio success. The first is the degree to which a company can offer products for which there is sufficient demand and optimize for volume/price trade-offs between public- and private-paying markets. The second is the degree to which a company can take advantage of brand loyalty and awareness in Africa. Safety is a primary concern in Africa given the penetration of counterfeit and substandard medicines. Consumers of medicines and other goods actively seek quality products and are brand conscious, “belying the view that the continent is a backwater where companies can sell second-rate merchandise.”38

Pharmaceutical companies need to assess the demand for their products and optimize for volume/price trade-offs. To identify the appropriate product portfolio for specific countries, companies need to first understand how their portfolio aligns with the various customer segments in a market and then prioritize accordingly, based on the various trade-offs between price, reimbursement and coverage (Figure 7).

FIGURE 7: A FRAMEWORK TO FACILITATE ALIGNMENT OF COMPANY PORTFOLIO WITH THE VARIOUS CUSTOMER SEGMENTS IN A MARKET

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<tr>
<th>Portfolio Segmentation</th>
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<tbody>
<tr>
<td>High</td>
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<tr>
<td>Low Volumes, Medium Margins</td>
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<tr>
<td>Oncology, non-essential vaccines, etc. Size of market dependent upon government healthcare spend.</td>
</tr>
<tr>
<td>Low Volumes, High Margins</td>
</tr>
<tr>
<td>Oncology, non-essential vaccines, aesthetic medicines, etc. Can be financed by insurance or individuals. Size of market is dependent upon size of the private market.</td>
</tr>
<tr>
<td>Price</td>
</tr>
<tr>
<td>Large Volumes, Low Margins</td>
</tr>
<tr>
<td>Typically drugs and vaccines on Essential Medicines List, etc.</td>
</tr>
<tr>
<td>Large Volumes, Low Margins</td>
</tr>
<tr>
<td>Typically OTC, anti-malarials, traditional medicines, etc., that most can afford.</td>
</tr>
<tr>
<td>Low</td>
</tr>
<tr>
<td>Publicly purchased drugs (including Donor and NGO purchased)</td>
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<tr>
<td>Privately purchased drugs</td>
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Source: BroadReach Healthcare, 2012
Each of these strategies can be adopted to reap opportunities in the public and private sector. In the public and NGO sector, high-priced drugs for oncology and non-essential vaccines offer a low volume, medium margin opportunity with market size dependent on spend. Higher margins can be achieved for these drugs in the private sector where their use can be financed by insurance or individuals. Conversely, drugs on the essential medicines list that are purchased by governments and NGOs are high volume but low price and low margin. Similar trends exist in over-the-counter (OTC), traditional and anti-malarial medicines in the private sector, reflecting their relative affordability.

Perhaps most surprising is that while most companies target the private sector, a significant and, in some cases, larger opportunity exists in the public sector given volume and long-term commitment. Common misconceptions about the complexity and competitive dynamics have often prevented MNCs from assessing how to leverage public tenders. However, neglecting the opportunity that exists could lead to companies missing out on long-term growth prospects within the public sector. In South Africa, for example, many companies continue to target the private sector despite the fact that the government spends over $500 million on medicines in public tenders.

Large revenues and long-term commitment can make tenders attractive, particularly as the private-paying market represents only a fraction of the potential in these countries. Companies such as Sanofi have won tenders worth billions of dollars in volume-based revenues and integrated distribution systems, and Aspen’s high volume, low margin model has secured the largest share of the HIV anti-retroviral (ARV) tender in South Africa.

There are two predominant types of public tenders:

1. **Commodity generic tenders** competing solely on price, and typically targeting essential drug list medicines which are often competitively won by Asian drug manufacturers. Here, companies need to revisit cost of goods sold, particularly with respect to older drugs, in order to be able to compete on price. Where companies are unable to compete on price, there are a number of pre-emptive measures they can take. They can leverage brand quality and guarantee of effectiveness to influence guideline development and drug use.
2. **Innovative product tenders** for more difficult-to-produce medicines such as injectables that are less open to generic competition. Premium and first-to-market products such as vaccines and novel anti-malarials can shape guidelines and demand a higher price. Countries issue innovative product tenders to attract new medicines to treat communicable (e.g., malaria) and noncommunicable (e.g., cervical cancer) diseases. Companies have more opportunity here to influence guidelines. For example, Novartis has been successful in supplying Coartem, the first fixed-dose combination therapy for malaria, in Zambia’s public sector through tenders. This success was built on a long-term relationship in which new medicines were preferentially provided at a favorable and affordable price point.

Some tenders explicitly value quality and value-added services. While currently nascent, this is a growing development across Africa with governments increasingly valuing quality over price to attract innovative and effective medicines. In Botswana, for example, medicine quality overrides price considerations in tenders, triggering high-profit potential despite a small market. In other countries, value-added services (e.g., support in the cold chain process through refrigeration supply) can make or break the tender decision. To compete on government tenders, it is essential that companies invest in stakeholder buy-in, understand budget allocation and generate unified government support.

**NGOs behave similarly to public payer channels, typically characterized in the high volume, low margin space.** NGOs have two advantages that pharmaceutical companies should consider. Firstly, they have access to multiple stakeholders across patients, KOLs, healthcare professionals and the government. They play a key role in accessing hard-to-reach populations in rural areas where in some cases they may be the only healthcare service provider. Secondly, many have existing infrastructure to distribute and monitor medicine use, particularly those funded by government and/or multi-lateral funding organizations such as the Global Fund for AIDS, Malaria and Tuberculosis. This existing medicine distribution and access infrastructure for patients could be an invaluable route-to-market for products offered by companies.

While existing systems are mainly set up for infectious diseases, NGOs are increasingly recognizing the value of offering services and medicines related to NCDs. This is especially the case with comorbidities: For example, diabetics are three times as likely to contract tuberculosis, and HIV patients on ARVs are at higher risk of developing diabetes and cancer. Currently, most medicines for infectious diseases like HIV are provided by Indian suppliers due to low prices and high quality generics. Additionally, pharmaceutical companies are not all welcome to collaborate with NGOs, many of whom have concerns about company intentions and operations. Nevertheless, overcoming existing barriers to collaborating with NGOs is a worthwhile assessment given their advantages.

In the **private sector**, GSK has been particularly successful in East Africa and Nigeria with a high volume, low margin model. Recognizing the affordability challenge, the company has replaced revenue with volume incentives and price capping at no more than 25% of the prices in developed countries. At the same time, it has proactively built brand loyalty by charging its least developed country (LDC) unit to spend half its time on business and half on reputation across 40 countries in Africa.
In the English-speaking countries, GSK is now the market leader. At the heart of this approach is long-term sustainability, a point underscored by GSK’s LDC unit head: “Not all LDCs will be LDCs forever and now is a really good time to invest to build a GSK footprint that benefits patients today and benefits our business in the longer term.”

For companies entering Africa, a common starting point in the private sector is to focus on key therapy areas and branded products, with emphasis on profitability and sustainability. Once a presence has been established, the portfolio can be expanded to priority areas, leveraging relationships and market insights built from initial entry. For example, in French West Africa, Sanofi began with a portfolio of largely innovator products commanding a premium price. Sanofi targeted these products to a small segment of the population to build brand awareness, gain market share and local market understanding. Over four decades since, the company has expanded its portfolio in the region, targeting a larger disease burden.

**Product safety and customer brand loyalty are important contributors to a successful and sustainable business.** To convey product safety and generate brand loyalty, pharmaceutical companies, especially MNCs, can develop innovative product-related attributes to enhance the value proposition. For example, attributes that extend the shelf life, such as heat-resistant formulations, and mitigate counterfeit risk through special packaging can attract public and private payers. Additionally, packaging that includes special illustrations for illiterate patients can help ensure appropriate medicine use and consequently, uptake. Innovative technology such as use of text messages for supply stock management and telehealth can give companies a critical competitive edge.

Moreover, with sufficient money to make discretionary purchases, the growing middle class desires and is increasingly able to afford branded products. This sector is growing in size and demanding higher quality products and care, and represents a key opportunity for companies to set themselves apart. The importance of this population cannot be underestimated for companies looking to build or strengthen existing activities in Africa. Signs of increasing demand are ubiquitous: in Tunisia, for example, large numbers of Libyans are now seeking private treatment which is perceived to be of higher quality.

In Mozambique, Tanzania and Zimbabwe, private specialist hospitals have been established by African Medical Investments in direct response to “demand for quality, international standard healthcare from emerging middle classes, overseas investors, governments and health insurers.” These trends are compounded by concerns around the quality and source of local brands and generics from India and China and the larger issue of counterfeit and substandard drugs.

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*To convey product safety and generate brand loyalty, pharmaceutical companies, especially MNCs, can develop innovative product-related attributes to enhance the value proposition.*
SUCCESS IS DRIVEN BY A COMPANY’S ABILITY TO OVERCOME THE HURDLES IN THE PATH TO MARKET AND PATH TO PATIENT

There are many ways to overcome the hurdles in the path to market. All are contingent on rapport-building, local stakeholder buy-in and trust.

- **Strengthen the regulatory and approval process** by engaging local stakeholders to gain clarity on the application process, participating in regional harmonization efforts such as those led by the World Bank, and sharing expertise with government stakeholders. Such efforts will streamline the registration process within and across countries, particularly those aiming for regional harmonization (e.g., the EAC).

- **Navigate pricing and market access dynamics** to optimize the route-to-market. Companies can consider an intra-country differential pricing strategy to account for various patient segments according to their ability to pay. For example, Roche offers different preferential pricing models in emerging markets to “enable more patients to receive treatment while maintaining a sustainable business.”

To increase chances of public reimbursement, companies can invest in research to produce innovative medicines in high need across African countries and support local R&D efforts. Investment in developing innovative and highly needed medicines such as a malaria vaccine, medicines for multi-drug resistant tuberculosis and new antibiotics also stand a better chance of reimbursement. Local R&D efforts include engagement of local patient groups and physicians in clinical trials and implementation of local Phase IV post-launch trials and/or observational studies. Companies can also offer technology transfer deals to local manufacturers and/or government research institutes.

- **Bolster distribution channels** through trustworthy partnerships to optimize price without reducing margins. An effective distribution strategy is essential in Africa and partnerships again have a key role to play. In many cases, companies with no direct presence in the continent have chosen to outsource sales, marketing and distribution to an agent who in turn will delegate each of these functions to local parties. While this model can work, it is not without risk and can also result in distributors sub-distributing, adding exponentially to the price the patient must pay for a drug, and ultimately restricting affordability.

*An effective distribution strategy is essential in Africa and partnerships again have a key role to play.*
When faced with this situation, one top ten MNC successfully reduced the price paid by patients for medicines in Kenya, without reducing its margins, by establishing a more efficient distribution strategy with a trusted partner. The company worked with RTT Health Sciences, to address core issues in its supply and distribution chain. This included moving from a single agent to a multi-agent purchasing model, increasing order frequency from quarterly to weekly, warehousing medicines in a central place and selling them at a pre-arranged price between the MNC and local distributors. Through this collaboration, the company was able to reduce the price to patient by 44%, thereby increasing affordability and access, while tripling its sales in the region.

- **Enhance sales and marketing capabilities** by applying company expertise locally, deploying non-financial assets from headquarters and affiliates in marketing, demand forecasting and brand building. These skills can be applied to strengthen local operations and shared with partners to optimize the business. Opportunities also exist to leverage remote syndicated or dedicated sales forces.

- **Introduce anti-counterfeit measures** to minimize supply disruptions, improve health outcomes, generate strong brand loyalty and reduced false competition. Interventions include technical training and guidance for stakeholders to help monitor and track counterfeits, and product-specific initiatives, such as holograms and quality assurance labels, engagement with pharmacies to conduct batch testing, and investing in tracking technology (e.g., electronic stock management and SMS authentication). Sproxil’s Mobile Product Authentication (MPA) Solution delivered through IBM’s SmartCloud, for example, enables the authenticity of medicines to be validated via cell phones, and allows companies to determine the extent of counterfeiting in regional supply chains.44

Public awareness campaigns, working with other companies and leveraging the media, can serve to increase awareness of the problem and its impact on health outcomes. Companies can also participate in the ongoing efforts of the Pharmaceutical Security Institute, working with other companies to help combat counterfeits.

Value-added services (VAS) with a commercial orientation can overcome hurdles in the **path to patient** and drive sales.45 It is important to assess which hurdles in the path are restricting patient numbers and recognize that although more patients may be aware of their condition or diagnosis rates may increase, these will not all translate into direct sales. The most effective approach to ensuring a greater number of patients are able to access and use appropriate medicines is to apply VAS which increase patient transition along the full path to patient.

- **Improve patient awareness**: Media engagement can be a powerful channel to raise disease and treatment awareness through public health campaigns, as well as build a strong brand. Engaging local KOLs such as celebrities, preachers, trade union leaders and other stakeholders can drive and support this process. Training for nurses and doctors can also serve to increase patient health literacy. Eli Lilly, for example, has driven awareness and product uptake in diabetes through the use of diabetes-specific initiatives in Nigeria, including the training of community health workers and provision of insulin and monitoring equipment for young diabetics.46
• **Expand healthcare access:** Companies can work with local organizations to find innovative ways of reaching out to patients and delivering healthcare services alongside medicine provision. Examples include partnering with government and non-government organizations, including missionary groups, to set up clinics and mobile health services where permanent infrastructure is nonexistent; and enhancing task-shifting efforts among staff with training for community health workers and nurses to provide health education and services. A recent initiative in India implemented by Novartis in partnership with local NGOs is an example for companies to consider in African countries. This educational initiative works through local village leaders and NGOs, with financial incentives for health workers. It has successfully encouraged more rural inhabitants to seek health advice (measured by an increase in doctor consultations from 9 to 23 percent), while at the same time increased awareness of and demand for effective medicine.47

• **Facilitate diagnosis:** Services built around improving diagnosis may include bundling medicines with low-cost testing/screening tools such as sphygmomanometers and stethoscopes for blood pressure, or providing fee-for-service incentives to community health workers to counsel and test patients for diseases in their homes.

• **Support treatment:** Programs supporting continual medical education (CME) and physician detailing techniques can fill gaps in or improve access to information among clinicians. Not only can such efforts ensure that medicines are appropriately provided to patients but they can also secure brand loyalty with clinical KOLs. In building brand loyalty through CME efforts on disease symptoms and modern treatments, companies can take advantage of limited or nonexistent generic substitution policies. Detailing doctors and pharmacists in Africa is highly effective to further commercial goals given their belief in a brand’s safety and efficacy.

Other activities to improve the path to patient can include innovative financing through PPPs, private sector engagement and corporate social responsibility (CSR).

• **Innovative financing:** By engaging in PPPs, companies can support medicine access and responsible use and learn from existing initiatives. Examples include GSK’s collaboration with the Malaria Vaccine Institute of PATH, the Bill and Melinda Gates Foundation and other NGOs to develop RTS,S/AS01, a malaria vaccine now in Phase III development; Botswana’s Comprehensive HIV/AIDS Partnership involves private partners and the government, each committing US$50m over five years through PPPs, private insurance engagement and CSR.

• **Private sector engagement:** MNCs can invest to develop and expand healthcare providers and suppliers of healthcare in the continent. There are many examples of this approach. PharmAccess’ Investment Fund for Health in Africa, a €50 million private equity fund is responding to the growing need for capital investments in Africa’s private healthcare sector. Africa Health Fund invests in healthcare-strengthening efforts alongside investment returns. For example, the fund made an investment in December 2009, acquiring a stake in a women’s hospital in Nairobi. Profits from the hospital’s private sector services subsidize free-of-charge service provision for HIV/AIDS patients and to support gender violence recovery.48
• **CSR:** Companies can also invest to align their CSR activities with their commercial interests, by first assessing how to reduce barriers between foundation-related or philanthropy work and the commercial strategy team, then identifying path-to-patient barriers that can be addressed through CSR/philanthropy-related work. These efforts can strengthen reputation and brand loyalty in targeted groups. As noted by Sebastian Fries, former Director of Strategic Planning for Africa, Middle East and Latin America at Pfizer: “The primary goal of our philanthropic activities is improvement in the provision of healthcare for the local population and improved access to our medicines.”\textsuperscript{49}

The CSR approach has been successfully leveraged by Pfizer in Nigeria to ensure a positive company image and boost sales. A market leader for CV treatments, the company has established a CV Summit Faculty Board made up of leading medical practitioners to serve in an advisory capacity on the management and treatment of CV disorders within the region. Members offer advice on relevant topics/modules and modalities for future CV regional/district summits. According to Pfizer, this is an educational platform for healthcare practitioners to engage in a robust discussion on latest trends in CV disease and its management.\textsuperscript{50}

Additionally, appropriate differential pricing across countries can be part of a CSR strategy and can facilitate broader market access. For example, since 2001, Novo Nordisk has been offering insulin products to public payers in Least Developed Countries (LDCs) at prices not exceeding 25% of the average price in industrialized countries.\textsuperscript{51} GSK, which has recently merged business and CSR goals in a single operating unit, has a goal of increasing volumes fivefold in Africa over the next five years. This new unit charges no more than a quarter of the UK price for GSK’s patented drugs, while off-patent medicines are sold at a small premium to the cheapest Indian-made generics. Finally, 20% of the unit’s profits are put into building healthcare infrastructure, supported by charities such as Save the Children and CARE International.\textsuperscript{52} While GSK was concerned with the potential effect of differential pricing on the risk of parallel trade and inappropriate reference pricing across countries, this concern has not manifested in their experience.

“To succeed in Africa, you need a holistic approach considering price and product, but as importantly a high focus on networking with local stakeholders, recruiting and keeping talented teams to get very close to the evolving and risky market environment. It may take time but what you do now will have direct importance longer-term.”

Sanofi
AFRICA’S POTENTIAL WILL REWARD COMMITMENT, ENGAGEMENT AND A BUSINESS MODEL THAT STRENGTHENS THE PATH TO MARKET AND PATIENT

The forecasted pharmaceutical market growth in African countries has already generated interest both among companies with existing African operations and those that plan future presence. From MNCs to Indian and Chinese generics manufacturers, pharmaceutical companies from all over the world are attracted by increasing African economic strength and the potential of its emerging middle class. These factors are triggering a rising demand for healthcare services and medicines, offering a strong growth opportunity for the companies with the right sustainable business model.

In some ways, harnessing the available opportunity requires a similar approach to one applied in traditional markets: general determinants of market attractiveness and assessment for location, operations and portfolio selection are key. However, the specific complexity and heterogeneity of the African opportunity requires companies to identify innovative ways to overcome hurdles in the path to market and path to patient. Some best practices can be gained from market-leading companies such as Sanofi and GSK. For example, a decentralized strategy with locally-led decision making and stakeholder engagement contributes to operational success and sustainability. Value-added services with a commercial orientation generate brand loyalty and increase medicine uptake.

Hurdles notwithstanding, there is a very real opportunity for the pharmaceutical industry in Africa. This will require long-term commitment and willingness to navigate the complexities and make difficult decisions to optimize margins, volumes and the investment required to build the path to market and patient. Engagement with this market now and in the long term will provide a robust platform for companies to shape the pharmaceutical industry dynamics alongside the broader healthcare environment in Africa.

This opportunity has never been as ripe for the taking •
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