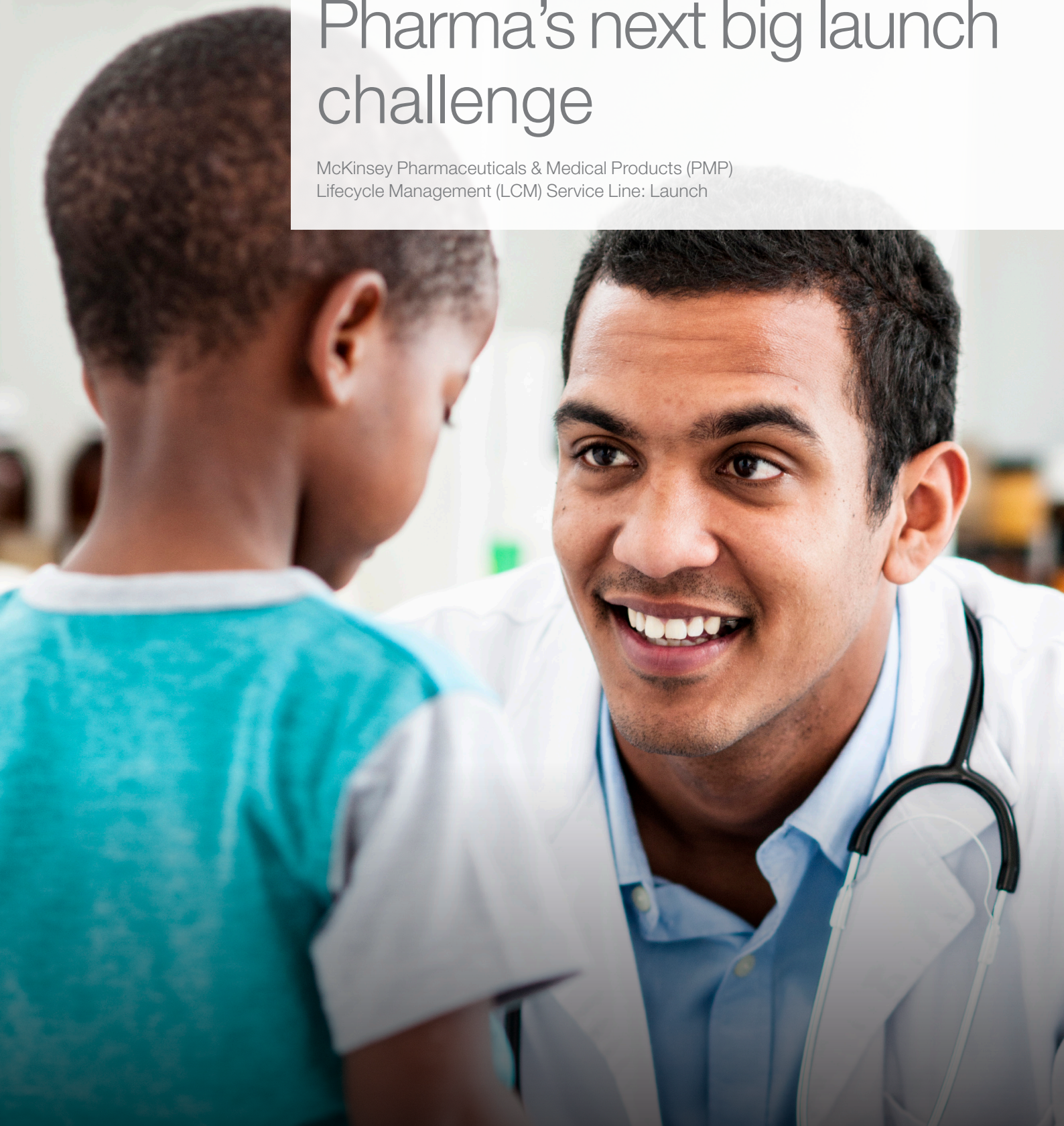


Accelerating access in emerging markets: Pharma's next big launch challenge

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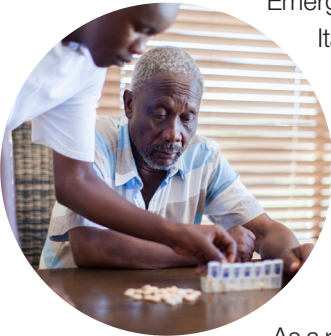


Accelerating access in emerging markets: Pharma's next big launch challenge

As developed markets continue to stagnate, emerging markets are becoming ever more important as a source of revenue growth for multinational pharmaceutical companies. However, many companies are finding that their traditional business models are not well equipped for gaining access in these markets, in particular for specialty and high-cost products. What's needed is a rapid shift from a marketing and sales focus to an access-driven commercial model – a transition that will require a considerable capability upgrade in both country and regional organizations. Accelerating access must be a core focus of launch planning in emerging markets.



UNDERSTANDING GROWTH OPPORTUNITIES AND BARRIERS

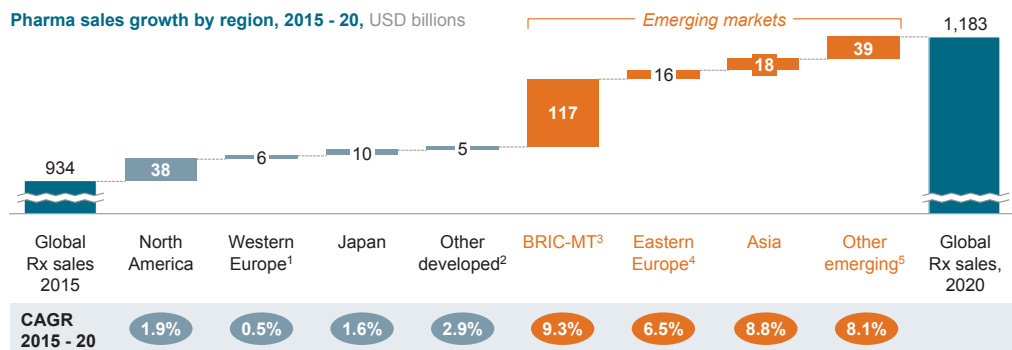


Emerging markets have now overtaken the EU5 economies (Germany, France, Italy, the UK, and Spain) in pharmaceutical spending, with a total market size of USD 281 billion compared with the EU5's USD 196 billion in 2014. As developed economies continue to constrain or cut healthcare funding, governments in many emerging markets are making healthcare a priority. They are investing in infrastructure, funding services, encouraging the development of a domestic industry, and expanding health insurance to a broader population.

As a result, emerging markets will be an important contributor to pharma sales growth over the next few years. Between 2015 and 2020, they are expected to account for USD 190 billion in sales growth, of which approximately 40 percent will come from innovative drugs.¹ Much of this growth is likely to be driven by Brazil, Russia, India, China, Mexico, and Turkey (the BRIC-MT countries), as indicated in Exhibit 1.

Emerging markets contribute materially to pharma growth over the next five years

Exhibit 1



¹ Austria, Belgium, Switzerland, Germany, Denmark, Spain, Finland, France, UK, Greece, Italy, Netherlands, Norway, Portugal, and Sweden

² Australia, Hong Kong, New Zealand, Singapore, South Korea, and Israel

³ Brazil, Russia, India, China, Mexico, and Turkey

⁴ Belarus, Bulgaria, Czech Republic, Croatia, Estonia, Hungary, Lithuania, Latvia, Moldova, Poland, Romania, Slovakia, Slovenia, Serbia, Ukraine

⁵ Algeria, Angola, Antigua, Argentina, Bahamas, Bahrain, Barbados, Belize, Benin, Bolivia, Botswana, Burkina Faso, Burundi, Cameroon, Cape Verde, Central African Rep., Chile, Columbia, Congo (DRC), Congo-Brazzaville, Costa Rica, Cote d'Ivoire, Cuba, Dominica, Dominican Republic, Ecuador, Egypt, El Salvador, Equatorial Guinea, Eritrea, Ethiopia, Gabon, Gambia, Ghana, Grenada, Guatemala, Guinea, Guyana, Haiti, Honduras, Iran, Iraq, Jamaica, Jordan, Kenya, Kuwait, Lebanon, Libya, Madagascar, Malawi, Mali, Mauritania, Mauritius, Morocco, Mozambique, Namibia, Nicaragua, Niger, Nigeria, Oman, Panama, Peru, Puerto Rico, Qatar, Rwanda, Saint Lucia, Saint Vincent, Saudi Arabia, Senegal, Seychelles, Sierra Leone, South Africa, Sudan, Suriname, Swaziland, Syria, Tanzania, Togo, Trinidad and Tobago, Tunisia, Uganda, United Arab Emirates, Uruguay, Venezuela, Yemen, Zambia, Zimbabwe

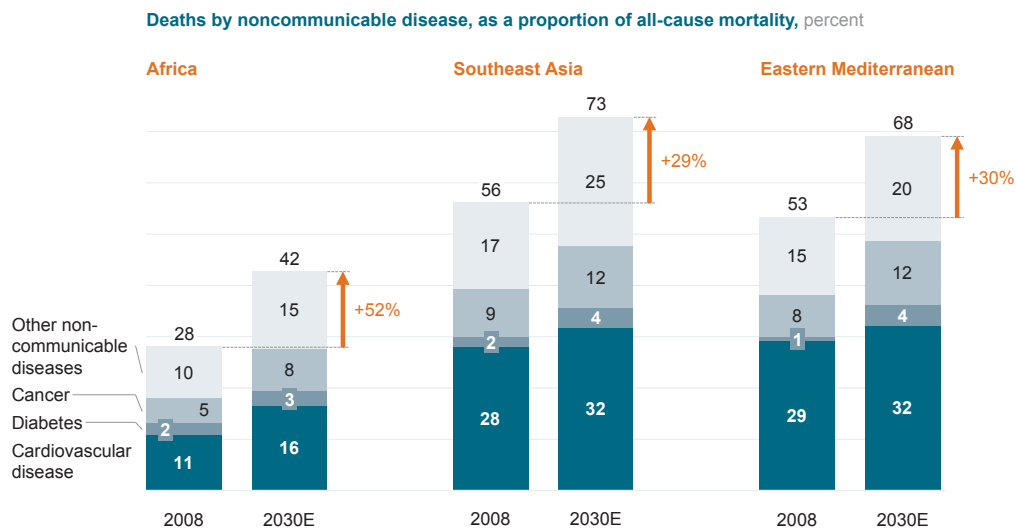
Source: BMI Research 2014; McKinsey analysis

Not only the size but also the nature of the pharmaceutical market is changing in emerging economies. As more people gain access to healthcare and populations shift to urban areas, noncommunicable diseases such as cancer, diabetes, and cardiovascular diseases are becoming more prevalent (Exhibit 2). This opens up opportunities for global pharma companies with portfolios covering these disease areas.

¹ "The global use of medicines: Outlook through 2016," IMS Institute for Healthcare Informatics, July 2012.

Noncommunicable diseases are on the rise in emerging markets

Exhibit 2



As emerging-market governments expand their healthcare provision, they are also looking for ways to contain its costs. A lack of experience in performing sophisticated cost-benefit equations can sometimes lead to simplistic price comparisons and crudely applied budget limits that deny patients access to innovative therapies. Beyond cost-benefit assessment, political pressures can also impact on market access decision making. When access is granted, price controls are often used to manage healthcare spending and encourage the development of the domestic industry. In China, for instance, the various provincial governments have introduced different tendering measures aimed at narrowing the price gap between local generics and off-patent international brands. In addition, hospital level reimbursement budget control policies have limited physicians' ability to prescribe higher priced off-patent international brands, at a time when local generics are still perceived to have discrepancy in quality. Such policies once limited to tier 1 cities in China have now been widely adopted across the country. The Russian government, as another example, grants substantial access and price advantages to locally manufactured products in public tenders, and operates an effective price freeze for imported medicines on the essential drugs list (EDL). In Brazil, the government also gives preference to locally manufactured products and is looking to reduce long-term cost, particularly of biologics, through a broad technology transfer agenda, which guarantees volumes to partners.

This growing focus on cost containment is not the only difficulty global drug companies face in securing market access in emerging economies. Other complicating factors include interpretations of intellectual property protection that favor generics and biosimilars, policies and practices that support local manufacturers, and frequent policy changes. Not surprisingly, pharma executives are starting to pay more attention to market-access capabilities as a means to capture the growth opportunities that emerging markets offer – especially for launches of innovative drugs.





RETHINKING MARKET ACCESS



In developed economies, market access is chiefly concerned with pricing and with satisfying local conditions, such as obtaining the appropriate ASMR and SMR ratings² in France. In emerging economies, the challenge is more complex. Drug companies seeking market access for their products are usually competing for attention and funding not just with other pharma companies and other disease areas, but with defense, education, and other government-funded sectors. At the same time, healthcare spending is lower than in developed economies. In 2012, public health expenditure amounted to 6.3 percent of GDP in Turkey, 6.3 percent in Russia, 5.4 percent in China, and 4.0 percent in India, compared with 9.4 percent in the UK and 11.3 percent in Germany.³

This complexity means that multinational drug companies need to define market access in a broader and more integrated way in emerging markets, to cover three core areas. The first is *regulatory*: obtaining marketing authorizations in a timely manner through initiatives such as securing local medical share of voice at the prelaunch phase (for instance, by involving medical thought leaders in local late-stage clinical trials). The second area is *pricing and reimbursement*: securing appropriate price levels and inclusion in reimbursement lists by generating compelling local evidence and conducting successful interventions and negotiations. And the third area is *infrastructure*: addressing bottlenecks in healthcare infrastructure and health-system resources through initiatives such as supporting physician education in a specialty that is not sufficiently represented in a particular country.

In reality, access in emerging markets is often a hit-and-miss affair. Pharma executives report that countries with similar disease profiles and levels of pharmaceutical spending can differ widely in their consumption of the same drug. This suggests that some teams are more successful than others at engaging local stakeholders and tailoring access initiatives to local contexts.

While there is no single key to unlock local market access, tackling common barriers at country level is a good place to start. One such barrier is *scarcity of funding*: emerging markets have lower per capita healthcare spending and often reserve it for basic therapies, offering access to innovative treatments only exceptionally or focusing only on priority disease areas (e.g., HIV vs. HCV in Brazil). Another barrier is *policy gaps*, ranging from weak protection of intellectual property to lax regulation of biosimilars. *Dependence on local partners* can also be a barrier in markets that are too small to justify a direct presence or require global businesses to act through local partners. The need to manage five to ten partners can make the task of ensuring compliance and performance highly complex. In addition, the *absence of local data* in countries without patient registries or epidemiological data hampers stakeholder discussions about budget management and the key issues and unmet medical needs of the local health system. *Infrastructure gaps* are a common barrier in countries where infrastructure does not exist at scale (such as in sub-Saharan Africa or rural areas in Brazil) or where

² SMR is an assessment of a drug's medical benefit or therapeutic value; ASMR is an assessment of the improvement of medical benefit it offers relative to other drugs or therapies.

³ World Bank at <http://data.worldbank.org/indicator/SH.XPD.TOTL.ZS>.

funds are insufficient to maintain it (as in Russia, which has 9.5 beds per 1,000 inhabitants compared with 2.9 in the US, but a per capita healthcare spend of just USD 887, compared with USD 8,895 in the US).⁴ Finally, many emerging markets suffer from a *lack of educated healthcare professionals*. In some rural areas, even primary-care physicians are in short supply, and in China, fewer than 30 percent of healthcare professionals (physicians and nurses) have a college degree or above.

To overcome these barriers, companies need to shift the focus of their commercial models from marketing and sales to access, and from brand-by-brand access planning to integrated cross-brand planning. Some leading pharma companies have had success in implementing access-driven models. For example, Roche developed a pricing program in the Philippines that takes into account what a patient can afford to pay. Patients prescribed Herceptin undergo a means test carried out by an independent agency, and are granted a discount if they are unable to pay the full price. Novo Nordisk has pioneered a multi-party public-private partnership in Kenya to address barriers in awareness, infrastructure, and affordability and reach 40,000 diabetes patients with its insulin products. Baxter launched the “Flying Angel” program in China in partnership with the Ministry of Health to address awareness, access, and affordability challenges of peritoneal dialysis (PD) among rural ESRD patients. Baxter invested in training of nephrologists and nurses in county hospitals as well as into logistics system expansion, whereas the government introduced treatment guidelines in rural areas, conducted hospitals certification of PD treatment, and subsidized rural patients through lowering the co-payment ratio.

Most successes so far have been confined to individual markets and based on ad hoc initiatives. Few pharma companies have a clear cross-market view of what best practices in access look like. Yet they need such a perspective to measure their access performance objectively and target interventions to improve it.

Companies also need to put more resources into access. McKinsey analyses show that country organizations in developed markets have 7 to 10 percent of their commercial staff dedicated to access, but only 3 to 5 percent in emerging markets. The reason probably lies in traditional mindsets that find it easier to justify incremental investment in a sales representative than in an access “overhead.” The lack of dedicated managers means that access tasks are often distributed across multiple roles, so that marketing professionals perform product-specific access tasks on the side, for instance. This leads to fragmentation and impedes the development of specialized access skills. Clearly, this hampers access success for new, innovative therapies in emerging markets.



⁴ World Bank.



ADOPTING A SYSTEMATIC APPROACH



Shifting to an access-driven commercial model at the country level represents a major business challenge, and needs to be treated as such. Simply handing out manuals and holding workshops with country teams, as some companies do, will not be enough to shift entrenched mindsets and behaviors. Other companies have outsourced access capabilities to local third parties; but, although this can lead to short-term gains, it can easily backfire if a pharma company finds its interests are no longer in synch with its partner's over issues such as compliance with pricing guidance. And, if this happens, country organizations may no longer have the capabilities to take responsibility for access back in house.

We believe that pharma companies need to approach access systematically, starting at the top. Access should be one of the few priorities on senior executives' agendas in emerging markets. It should be central to the overall strategy for the region and any business transformation initiatives that originate from it. Successful programs also need to be anchored in cross-functional plans at country level. These plans should include both transformational initiatives that take time to make an impact and incremental short-term initiatives that generate quick wins to bolster momentum.

Ensuring that access plans score highly on quality and differentiation can be difficult, as local country teams often don't know what they don't know. To transform the way country organizations think about and act on access opportunities, companies need to take a few symbolic actions that make people sit up and take notice.

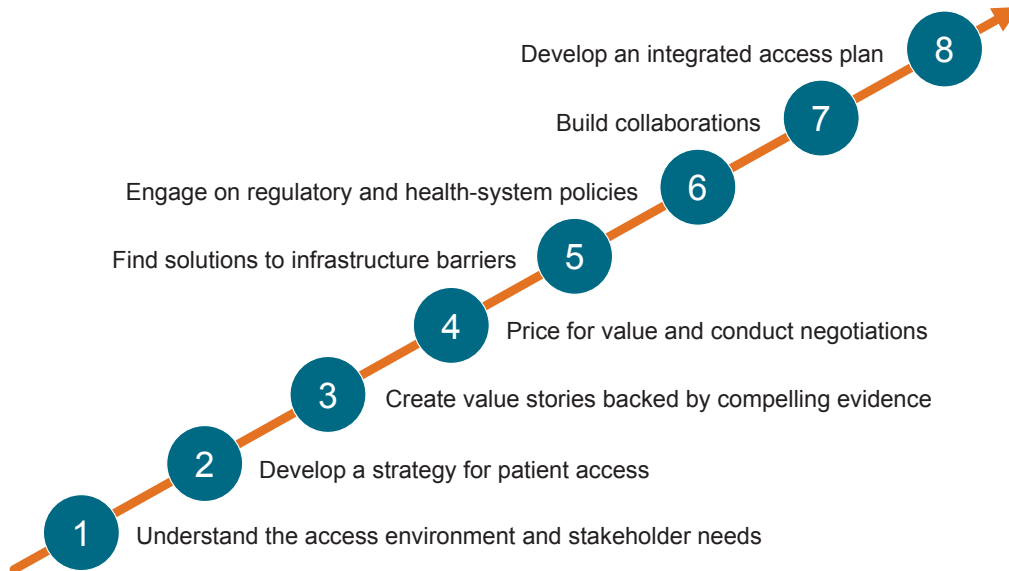
In our experience, a company making the shift to an access-driven commercial model can get off to a good start by running a diagnostic of the external environment and its internal capabilities. The external diagnostic will help it build an understanding of local access trends, current and potential sources of business, and challenges in the route to market. The internal diagnostic should reveal whether the company has the capabilities to overcome local access barriers, and where any gaps lie.

To help with this diagnostic, McKinsey has developed a framework that groups access capabilities into eight clusters (Exhibit 3):

- 1. Understand the access environment and stakeholder needs.** Market access happens at a local level, so country organizations need a good understanding of both the local access landscape and the stakeholders who shape it. That means not just those with formal responsibility for access decisions, but also those who influence them, who may not be so well known but can be identified through an analysis of informal networks. Best-in-class companies map stakeholders by constantly taking information from their medical, sales, marketing, and access teams and sharing it across the organization.
- 2. Develop a strategy for patient access.** To improve access, companies need to look at barriers from the patient's point of view. Do barriers lie in awareness, for instance, or afford-

An eight-part framework helps companies diagnose their access capabilities

Exhibit 3



ability, or even a lack of public transport to the hospital? Most access plans build on insights from the annual brand plan, but the best include longer-term measures to improve patient access, such as a collaboration with NGOs to set up a dedicated fund for a rare disease.

- 3. Create value stories backed by compelling evidence.** When local data is not available, other data can be tailored to the local context to create a compelling value story for payors and policy makers. Standard practice is to take value stories developed for the US or Europe and complement them with publicly available local data. Great practice is to generate missing local data, for instance, by partnering with local institutions or working with payors to set up a local patient registry.
- 4. Price for value and conduct negotiations.** Pricing in emerging markets is often decided by the global team, limiting the leeway local teams have in negotiating prices and terms. Successful companies dedicate at least one member of the access team to pricing and provide solid training on negotiating and designing innovative pricing approaches that find ways to offer access despite the limits on public funding.
- 5. Find solutions to infrastructure barriers.** Building infrastructure is not a task for a pharmaceutical company, but a sound access strategy could include facilitating public-private partnerships with construction companies or personal insurance providers, for instance. Great access strategies tackle infrastructure barriers as part of a broader approach to addressing diseases: for instance, by offering a combination of diagnostic and treatment options. Local know-how on structuring public-private partnerships is vital to the success of such approaches.
- 6. Engage on regulatory and health-system policies.** Although emerging markets are undergoing rapid development in their regulatory and health-system policies, few pharma



companies engage in actively shaping them. Best-in-class organizations develop the skills to do so and hire senior government affairs managers who can provide appropriate support to policy makers.

- 7. Build collaborations.** Companies often enter partnerships opportunistically rather than crafting a long-term collaboration plan as part of their access strategy. Effective collaborations could involve working with patients' and physicians' associations, payors, and regulators to improve access and health-system performance.
- 8. Develop an integrated access plan.** It is critical that the market access team is aligned with the commercial teams on priorities for brands and access initiatives. The brand plan should include detailed market access strategies at country and regional level and a unified plan across the portfolio to coordinate stakeholder engagement. It should also specify who in the team is accountable for developing and implementing the market access strategies.

The other essentials of a successful access approach are a cross-functional local team to ensure that messages are fully aligned across market access, sales, marketing, and government affairs, and a fully engaged general manager or "chief access officer" (see sidebar).

Although access needs to be owned and driven at country level, some activities still need to take place at regional level, such as connecting stakeholders (for example, region-wide patient organizations), facilitating data collection and analysis, and sharing best practices between markets. To support these activities, regions should put in place critical enablers such as platforms for exchanging experiences and initiatives to kick-start capability building. In addition, regional teams should provide country teams with challenge and support as they develop their local launch and access plans.

Chief access officer: The role of the country manager

The country manager is responsible for acting as the chief access officer both inside and outside the local organization. Whenever we have seen multi-nationals achieve successful access in emerging markets, it was this individual's commitment that made it happen at the local level.

Externally, country managers need to build relationships with policy makers, policy shapers, and other medical and non-medical stakeholders. We find that individuals who speak the local language and have at least five years' experience in the role do best at the vital task of embedding themselves in the local environment. Another prerequisite is the ability to hold discussions that go beyond products to include health systems, disease pathways, public-private partnerships, and other topics. To engage minister-level stakeholders and decision makers, country managers need presence, gravitas, and strong communication skills.

Internally, country managers need to keep their team on course, work across organizational units, identify capability gaps, and attract and develop talent. When hiring government affairs managers, some country managers target specialists from other industries, such as beverages or telecommunications, as success in this role is driven much more by personality than by medical or pharmaceutical knowledge. Effective country managers also insist that access talent is based not in the country organization's head office, but in the cities where key external stakeholders are located. It is the country manager's job to create an environment that makes access a desirable career stepping-stone and attracts and retains top talent.





BECOMING AN ACCESS-DRIVEN ORGANIZATION

In our experience, the pharma companies that lead the pack at gaining market access in emerging countries share a number of common success factors.



Senior leaders begin by making market access one of their top three priorities in emerging markets. Companies then craft a distinctive approach to access by exchanging knowledge and shaping a common language across geographies and functions. They challenge the thinking of country general managers and teams by providing local and cross-industry insights into what great access looks like, and run capability-building programs for local practitioners, anchoring learning in the local business context through months-long “field and forum” approaches. To kick-start innovative strategies and quick wins, they design “lighthouse” projects that attract attention and can be rapidly replicated across countries. Finally, they sustain their focus on access for years and commit country-level and regional resources to achieve transformational change.



Emerging markets represent a major opportunity for pharmaceutical companies seeking revenue growth. To capture it, they need to make a rapid shift from traditional marketing and sales approaches to access-driven commercial models. Winning companies are embracing this shift as a priority in emerging markets. To master it, they are systematically investing in capability building across emerging markets.





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