WHITE PAPER

Pharma's dilemma: Cracking the code of access in low- and middle-income countries

How to crack the code of access

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Pharma's dilemma: Cracking the code of access in LMICs

With approximately 6.82 billion people living in emerging and developing markets across Asia, Africa and Latin America, low- and middle-income countries (LMICs) present a compelling opportunity for pharmaceutical manufacturers. Yet the potential is paired with a stark dilemma: What to prioritize, when to act and how to navigate the complex landscape of access?

For pharma companies seeking to expand their reach, navigating access in these countries is no longer just about market entry but about addressing systemic barriers like pricing constraints, infrastructure limitations, regulatory complexities and fragmented healthcare systems. The question isn't just how to reach these markets—it's how to tailor solutions that balance business value with genuine impact and where to focus resources amid varying local needs and challenges.

The stakes are high. Prioritizing the right regions, engaging with local stakeholders and building sustainable models that can adapt to both economic and political shifts all require a deep understanding of the landscape and a flexible, nuanced approach. How can manufacturers position themselves not just as suppliers of medicine, but as partners in building stronger healthcare ecosystems?

The answer lies in rethinking access strategy—starting with the basics of "When?", "Where?" and "How?".

LMICs: A strategic imperative for pharma

The global healthcare landscape is transforming. Pharmaceutical manufacturers, traditionally reliant on U.S. and European markets, face challenges due to cost control, regulatory measures and intense competition. To diversify, they are turning to emerging markets, particularly LMICs.

LMICs are home to approximately 84% of the world's population. They have been growing three times faster than developed economies since 2005. As economic metrics in LMICs have improved, their healthcare focus is shifting from infectious diseases to chronic non-communicable diseases, creating new opportunities for pharmaceutical companies. These markets provide pharmaceutical companies with a chance to leverage mature products, penetrate underserved regions and address significant unmet healthcare needs. Although it's not a major profit driver, the expansion into LMICs offers a strategic opportunity for incremental growth for pharmaceutical companies.

Yet the complexity of LMIC markets requires a tailored approach. Product suitability plays a key role, with oral therapies presenting the most viable opportunities due to easier distribution and administration requirements. While injectables can also succeed, high-cost

treatments, such as CAR-T therapies, face hurdles in many LMICs due to affordability challenges, limited healthcare infrastructure and logistical constraints like cold-chain requirements. Still, the landscape is not uniform—countries like Brazil, with more advanced payer systems and regulatory frameworks, can support complex therapies, whereas less-developed regions, such as parts of sub-Saharan Africa, may present significant barriers to entry.

Beyond business considerations, expanding into LMICs aligns closely with the environmental, social and governance (ESG) objectives of pharmaceutical manufacturers. By improving access to essential medicines and addressing healthcare disparities, companies can play a pivotal role in enhancing global health outcomes while achieving sustainable growth.

In this evolving global healthcare landscape, LMICs offer pharmaceutical companies an opportunity not just to expand their presence, but to redefine their role as enablers of equitable healthcare. With the right strategies, companies can navigate the complexities of these markets and contribute to a healthier, more sustainable future.

Roadblocks to enter LMICs

Despite the improving macroeconomic indicators, manufacturers must navigate several challenges when entering LMICs.

- **Lack of healthcare infrastructure:** One of the biggest challenges in LMICs is the lack of healthcare infrastructure. A 2018 report by the Lancet Global Health Commission found that 2.9 million lives are lost in LMICs due to lack of access to care, and another 5.7 million people die due to the inadequate quality of healthcare. Additionally, the World Bank estimates that LMICs have less than one physician per thousand people in their populations, in contrast to high-income countries, where there are about 3.5 physicians per thousand.

- **Lack of government funding and high out-of-pocket spend:** The lack of healthcare access in LMICs is exacerbated by insufficient government focus. Political and economic instabilities contribute to this issue, but for noncommunicable diseases, the lack of access is often due to inadequate government policy and economic support. Additionally, government funding for healthcare in LMICs is significantly lower compared to upper-income countries. While the average per capita health expenditure by the government in upper-income countries is around $4,500, in LMICs, it is less than $500.

  Even when governments fund public healthcare, this funding is often targeted at those living below the poverty line or it is only partially funded with an annual cap. Private health insurers offer coverage in some markets, but this coverage is mostly accessible to high-income earners or through select employers offering this benefit. Consequently, the majority of the population faces high out-of-pocket costs and cannot afford innovative medicines, making low drug affordability a significant barrier for innovative medicine manufacturers.

- **Burdensome regulatory process:** The regulatory environment in LMICs varies considerably across countries. Usually, the timing from regulatory filing to approval can be anywhere between two to four years, with most markets favoring drugs that are already on the WHO (World Health Organization) Model List of Essential Medicines. For other products, approval would rely on a number of factors. For example, Indian regulators are increasingly demanding the availability of randomized controlled trial data conducted on local populations. Regulators in the Philippines, who have adopted a health technology assessment model, require cost-effectiveness and budget-impact models for their assessments.
- **Lack of long-term organizational commitment:** To successfully enter emerging markets requires a commitment from senior leadership with a dedicated team to plan and execute market entry. Currently, many LMIC initiatives are a patchwork of C-suite-led ESG initiatives in the form of donations or marketing of mature products that have lost their patent in the U.S. and the EU.

Strategic considerations for LMIC market entry

To successfully enter LMICs, manufacturers need to develop a long-term, sustainable strategy that is built around these four steps outlined in Figure 1.

FIGURE 1:

5 steps to LMIC market commercialization

When to consider an LMIC strategy?

The timing of entry into LMICs varies widely based on the manufacturer's portfolio. For manufacturers with a large vaccine or anti-infectious-disease portfolio, entering LMICs almost simultaneously with the advanced countries is an approach they typically choose. The drivers for this approach are the desire to reach a larger patient pool and genuinely make a global impact in regions where it would matter.

The decision is nuanced when the portfolio is geared toward noncommunicable diseases. In such cases, manufacturers have been more cautious, often delaying entry until the products are close to losing exclusivity in high-income countries or sometimes after they lose exclusivity. Acknowledging the growing need for innovative products to treat noncommunicable diseases in LMICs and the improving economic and affordability landscape in some of these countries, manufacturers are considering the launch of their innovative products earlier in the product life cycle through different strategies that would mitigate their exposure to international reference pricing and other risks.

Prioritize markets: Where to enter first?

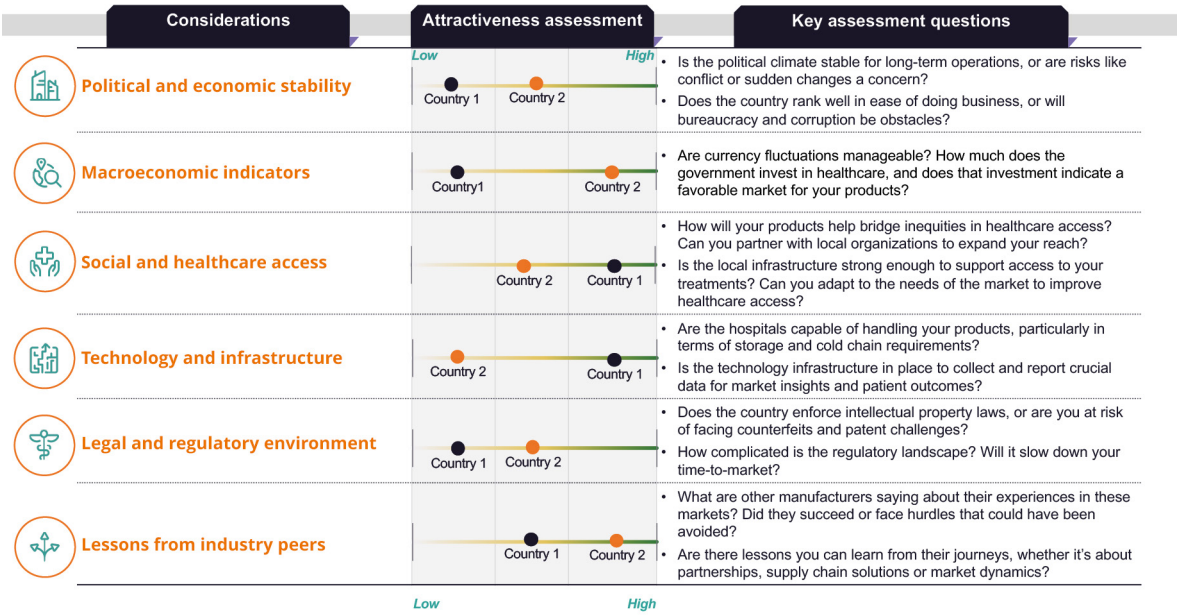
When expanding into LMICs, identifying the right markets is the first and most critical step toward building a sustainable strategy. It's essential to dive deeper into the key factors that shape the viability of each market. Consider the following questions:

1. Understanding political and economic dynamics helps avoid unexpected risks: How aware are you of the political and macroeconomic situation of target countries?
2. A country's economic health is often a bellwether for long-term success: How confident are you that your investment will withstand economic volatility?
3. Understanding the local healthcare environment means tailoring your approach: How can your business be part of the solution?
4. Without the right infrastructure, even the best products can fail to make an impact: How will the country's hospitals support your innovation?
5. Navigating local regulations can be complicated: How can you ensure your product is protected and compliant?
6. Looking to the experiences of others can save you time and resources: Will you draw the right learnings from the experiences of others who have already paved the way?

To navigate the complexities of market entry in LMICs, it's essential to adopt a structured approach. This Market Prioritization Framework (Figure 2) provides a clear path to evaluate and rank potential markets based on key factors that directly influence success, ensuring that investments are both strategic and sustainable.

FIGURE 2:

LMIC Market Prioritization Framework



By asking and answering these questions, manufacturers can build a strong foundation for market entry, avoiding common pitfalls and focusing on sustainable growth. Prioritizing markets thoughtfully ensures that your investments align with the opportunities available, ultimately driving success in LMICs.

Navigate regulatory and access pathways

Understanding the regulatory framework, data requirement and timeline is of paramount importance before manufacturers decide to launch a new product in any market. As we have stated, pharmaceutical products face a plethora of additional regulatory requirements in emerging markets that can delay approval by two to four years. In such scenarios, it's worth asking:

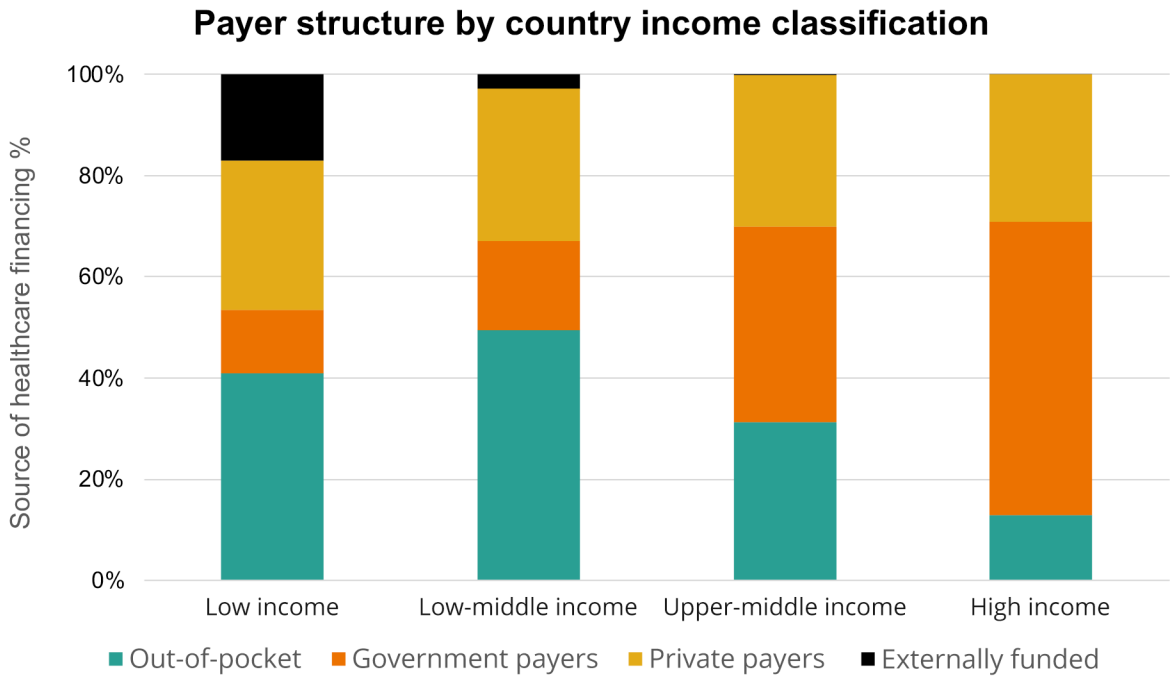
- How critical is the market for our LMIC strategy?
- Is the delay in approval acceptable?
- Are there any feasible work-arounds for regulatory approval in a given country?

Based on our experience, in some markets like Indonesia and Vietnam, regulatory delays may be unavoidable due to local bureaucracy. However, in others, regulators offer some flexibility. For instance, Indian regulators accept FDA and European Medicines Agency (EMA) data for approval, with a promise of future local studies. In Latin America, the Pan American Health Organization (PAHO) facilitates harmonization across smaller markets, expediting the evaluation and approval of drugs by recognizing approvals from regulatory bodies such as the Brazilian Health Regulatory Agency (Anvisa), the Public Health Institute of Chile (ISP) and the Federal Commission for the Protection against Sanitary Risk in Mexico

(COFEPRIS)—though final approval rests with each country's regulators. Alternatively, some manufacturers bypass the regulatory process by partnering with local health systems for direct product shipment.

FIGURE 3:

Payer structure by country income classification



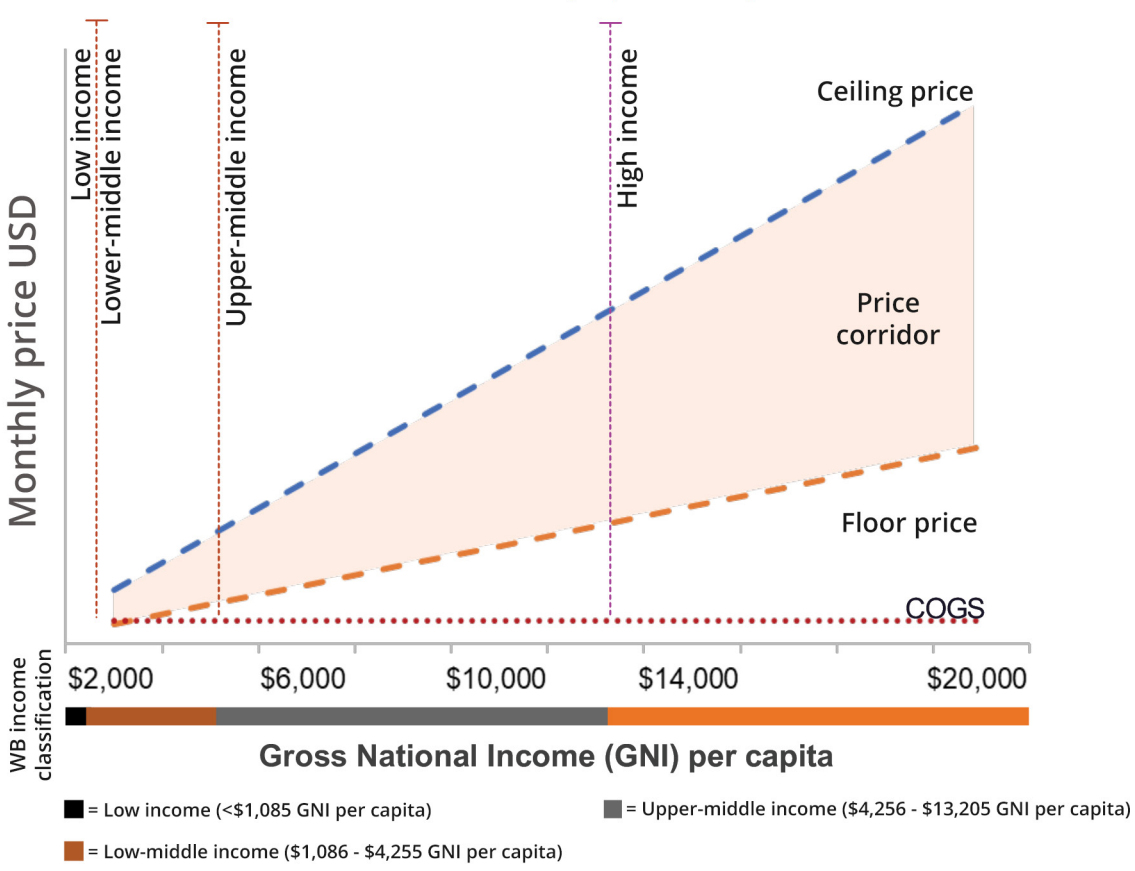
Source: 2021 World Bank Data

Reimbursement in emerging markets largely varies. Upper-middle-income countries like Brazil and China have a well-functioning public payer system, as well as a growing, well-funded private payer system. However, in most low-middle-income and low-income countries, reimbursement is challenging due to underfunded public payers focusing on the lowest economic strata, or a large population segment that relies on out-of-pocket payment to fund their healthcare costs. In these markets, manufacturers form partnerships to address reimbursement issues with central governments, state or provincial governments (for example, in India, most states have their own health insurance scheme; in Pakistan, the Sehat Sahulat program is public health insurance offered by the central and provincial governments in collaboration), large public employers (for example, the military, railways, etc.) and private employers. Private sources such as NGOs also play a crucial role in expanding healthcare access beyond traditional health plans.

Address affordability for long-term growth

FIGURE 4:

Price by GNI per capita assessment



GNI per capita - Gross National Income per capita for relevant countries as defined by the World Bank (updated annually)

In emerging markets, drug pricing and affordability are critical issues, due to the lack of well-funded government payers and immature private payer channels.

While high-income and upper-middle-income countries can absorb a wide price range due to a well-developed payer system, the affordability range gets narrower in lower-middle-income and low-income countries. The limited affordability in these markets adds significant downward pricing pressure, and manufacturers who consider reducing prices must wrestle with international reference pricing (IRP) implications. So how do manufacturers navigate this problem?

- **Marketing their mature products:** Manufacturers often market products that have lost or are close to losing exclusivity in the U.S. and EU. This allows them to reduce prices significantly in LMICs to compete with generics while leveraging quality and brand recognition.

- **Launching in-market drugs under a second brand name:** Manufacturers adopt Emerging Market Brands (EMBs) to launch drugs at reduced prices, sometimes up to 80% lower than prices in higher income regions. Launching an alternate brand in emerging markets allows manufacturers to offer an affordable option in price-sensitive markets.

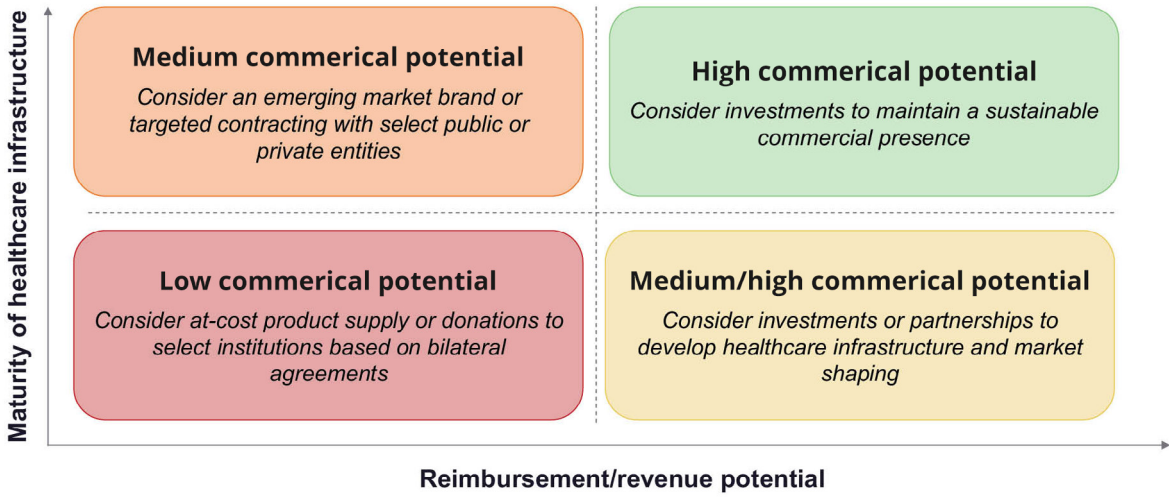
Even after the implementation of these strategies, given the immense income and wealth disparities in the low- and lower-middle-income markets, access to medicine is often limited to the upper-income segments in these markets, which can still be a substantial opportunity due to their large population base. To achieve deeper market penetration, manufacturers offer different types of patient access programs like:

- **Early access programs (EAPs):** Manufacturers design EAPs by considering various country-specific factors that influence their operability. These programs are tailored to meet the high demand for access to innovative drugs, particularly in regions where unmet patient needs are significant.
- **Patient assistance program (PAP):** Manufacturers are increasingly focusing on designing more flexible offerings tailored to specific brand and patient needs. These programs help make drugs more affordable for patients through options such as "buy one, get one" offers, free supplies after a set duration of purchases, flexible payment plans and tiered pricing models.

Develop an effective go-to-market (GTM) strategy

FIGURE 5:

Price by GNI/capita assessment



Given the diversity of LMIC markets, prioritization is essential to determine which countries offer the best commercialization potential and where market-shaping investments are most viable. After assessing multiple factors—investment potential, market access and expected reach—manufacturers typically categorize countries into four buckets, shown in Figure 5.

Companies can craft tailored GTM strategies based on this segmentation, helping them focus on and succeed in the most promising market.

While upper-middle-income countries like Brazil and China often qualify for the high commercial potential bucket, low-middle-income and low-income countries present unique challenges. These countries require careful evaluation to align on a suitable GTM strategy, as manufacturers face a lack of adequate healthcare and supply chain infrastructure. In large populous countries like India, the urban and ex-urban centers are dispersed across the country, making detailing and distribution difficult. In these markets, manufacturers must overcome hurdles to reach the appropriate physicians and populations that matter for their products.

Manufacturers address these challenges differently. In markets that merit a commercial presence, some manufacturers engage in voluntary licensing with local manufacturers with the necessary sales force and market experience for detailing and distribution in the country. Manufacturers uncomfortable with technology transfer typically handle promotion and distribution by selecting supply chain partners.

In other markets where establishing a commercial footprint is deemed too difficult, manufacturers rely on direct contracting and distribution of their products to select hospitals they partner with.

Tailor LMIC strategies by market

LMICs provide multinational pharmaceutical manufacturers with opportunities to diversify markets, reduce risks from price controls in the U.S. and EU, and achieve ESG goals through expanded patient access. Every LMIC presents unique challenges, ranging from filing to commercialization, requiring tailored strategies for each market.

We would like to thank Bill Coyle for his valuable input and feedback in developing this white paper.

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