White paper

QUINTILES®

Emerging markets:
Four entry strategies for small and midsized companies

Executive summary

Emerging markets offer significant untapped sales potential for biopharma companies, but bringing a new product to these markets can be complicated, costly and time consuming. This paper outlines the obstacles small and mid-sized biopharma companies face when entering emerging markets, the benefits and risks of different market access strategies, and how to choose an approach that delivers the most long term value to their business.

Improve your probability *of success*™

Table of contents

Great potential, unknown risk

There is no question that emerging markets represent a significant opportunity for the biopharmaceutical industry. The growth and increased age of local populations, improved prosperity, and government initiatives to bolster access to better healthcare are predicted to drive sector growth that will likely continue in the coming years. And the need in the communities for more robust pharmaceutical treatment options is substantial. Populations in these countries suffer from myriad chronic health issues, including diabetes, cancer, heart disease and others. China and India currently have the world's highest population of diabetics[1], in Russia cancer accounts for approximately 15 percent of all mortalities[2], and in Brazil cardiovascular disease and cancer are the leading causes of death and disability[3].

At the same time, growth in developed markets, including the U.S. and the UK, appears to be steadily slowing, with spending slightly below global averages meaning emerging markets aren't just a nice to have side business. In the coming years they are likely to represent larger swathes of sales volumes, making them vital to long term profitability. While these countries still have relatively low price thresholds, the large volume of need makes them important strategic destinations for biopharma companies, but only if they can develop targeted market plans that address the unique needs of local consumers, physicians, regulators and payers.

But bringing a new drug to market in Russia, Turkey, Mexico, Brazil or any other emerging market destination can be fraught with risk. Shifting regulations, lack of an existing sales network, unfamiliar marketplace mechanics, and uncertainty about local laws and IP protection are just a few of the challenges that biopharma companies face when they try to break into a new emerging market. Larger biopharma companies often have the time and resources to establish the necessary infrastructure, relationships and feet on the ground to establish their brand in these destinations, but for small and mid-sized companies who may have smaller pipelines, choosing the right strategy is more complicated.

Shifting regulations, lack of an existing sales network, unfamiliar marketplace mechanics, and uncertainty about local laws and IP protection are just a few of the challenges that biopharma companies face when they try to break into a new emerging market.

The right market strategy for you

There are four paths that small and midsized biopharma companies can choose when entering an emerging market. These include **partnering with big pharma; working with a distributor, going it alone, or partnering with a commercial solutions provider.** Each of these models offers a unique set of benefits and rrisks; however, choosing the approach that is right for a company will depend on their strategic intent. Maximizing both short term profit and long term value often presents conflicts, and companies will need to decide which to focus on based on the strategic importance they place on entering the market in question and their willingness to allocate incremental investment to entry in new markets.

Figure 1 – Comparison of market entry strategies with their trade-offs

Market entry strategies

A number of options with different trade-offs are available to partner

	Build own presence	Partner with pharma	Partner with commercial provider	Work with a distributor
Ease of implementation	○	◑	◑	●
Strategic control	●	◔	●	○
Economic benefit	●	◔	◑	◑
Capability level	◔	●	◕	◔
Local knowledge transfer	◔	○	◕	○
Focus on product without dilution	●	◔	◕	◔
Compliance, quality & governance approach	◑	●	●	◔

○ ◔ ◑ ◕ ●
Low Medium High

1. Work with a big pharma partner

When entering an unknown emerging market, many small and midsized companies often look for a partner who already understands the particular complexities that exist there. When possible, that partner will be a larger biopharma company that already has existing infrastructure, capabilities and networks in the country, and can help them navigate the legal and commercial landscape.

There are many short term benefits from this model. Partnering with big pharma eliminates a lot of the early entry risks and costs associated with building infrastructure and developing a team, while linking the unknown product to a well-established brand name and team. It also means they can likely ramp-up the sales cycle sooner than if they had started from scratch, all while requiring less time or effort.

But long term, the benefits of this model are less clear. When companies enter these partnerships they can often become a small fish in a very big pond. In most cases control of the sales strategy and product messaging is heavily compromised when relying on the partner to effectively deliver a product to market. Yet, a big pharma company's priorities will often be to build a market strategy that benefits their own portfolio first, which means the smaller company's product may get sidelined, the price may be lowered, or the dedicated sales team may be insufficient, limited to a niche market, or pulled in too many different directions. This can dilute the value of the smaller company's product in that marketplace, and lower the broader value of their product portfolio. The company also sacrifices the opportunity to build its local relationships, expertise and corporate brand presence in the country, limiting their ability to expand independently in the future.

2. Work with a distributor

Small and midsized companies may also opt to work with a global distributor for many of the same reasons mentioned above. These distributors have established networks and sales processes, and understand the rules and regulations governing the pharma marketplace. Like working with big pharma, this saves the smaller company the cost, effort and hassle required to build their own infrastructure, and they get the product to market more quickly. But again, the short term benefits may not be worth the long term sacrifices.

As with big pharma, smaller companies give up control of their market strategy and miss the opportunity to establish relationships with local KOLs when they work with a distributor. Often in these partnerships, the product may make it to pharmacy shelves, but with little targeted marketing effort or supporting sales initiatives, it can struggle to gain a foothold in new markets. And just like big pharma, distributors have a whole portfolio of products to sell and will accordingly make marketing decisions based on the needs of their entire portfolio – not just a single product.

These companies are also relying on distributors to understand and adhere to the intricacies of any regulatory issues related to their product, and the broader laws and regulations that govern that country's pharma sector. When choosing this model, they must do their due diligence to be sure the distributor's strategies align with their own corporate policies on these matters.

3. Go it alone

In the long run, going it alone is the most financially beneficial route to take, because it represents the best chance that the product will get the right marketing attention and product messaging, and that its value to the company will remain fully intact. It can also be an important step in a company's strategic plans if it is seeking to expand its global presence and to gain a permanent foothold in that burgeoning new market.

But in the short term, small and midsized companies will need to address many challenges in bringing this model to fruition. Entering an emerging market with no experience or infrastructure in place can be a risky process that requires significant time, investment and a willingness to make mistakes before the business team figures out the landscape for the product and the company. The rules governing each country are different, and business leaders need to be certain they are adhering to the laws and rules of that country, or they risk fines, delays and other obstacles that can setback their market plan. For example, in Brazil, a pharma company must have a legal entity established in the company's name before they can begin any regulatory submission processes. That means the company either has to purchase an existing pharma business, which can be expensive; purchase a shell entity established for this purpose, which can be less expensive but more risky; or build a corporation from scratch, which is arguably the safest choice but can add 18 months or more to the launch timeline.

Entering an emerging market with no experience or infrastructure in place can be a risky process that requires significant time, investment and a willingness to make mistakes before the business team figures out the landscape for the product and the company.

These companies also have to deal with all of the operational issues, including training sales reps, building relationships with physicians and regulators, confirming they have all of the equipment and labs necessary to do business, and making sure they understand and have completed all licensing steps, compliance requirements, and paperwork needed to legally bring that product to market.

None of these obstacles is insurmountable, but they do require significant capital and time to be successful, an important strategic consideration.

4. Partner with a global commercial solutions provider

The fourth option is to partner with a commercial solutions provider that acts as a seasoned representative and guide for that company in the marketplace. Small and midsized companies that chose this model get many of the early benefits of partnering with big pharma or a distributor, as well as the long term benefits of going it alone.

In the short term, they can take advantage of the extensive local knowledge and existing infrastructure, technology and headcount of the global commercial solutions provider who will have already established relationships with payers, providers, pharma and patient communities in that marketplace. This can also be provided from a support and administration perspective, comprising staffing, training, HR, IT and finance. These tools, relationships and teams can be immediately leveraged to support a new product market strategy, which will dramatically shorten the time it takes to bring that product to market.

This model does require an up-front investment on the part of the product owner, but in exchange, that company maintains full control of their portfolio, as well as the messaging, pricing and go-to-market plan. When working with a commercial solution provider, each product has its own dedicated sales force and strategy, so the marketing plan never gets diluted to meet the needs of another brand. And if the product owner's goals for that product change, the market strategy can be adapted to accommodate it. For example, the owner may decide to add or subtract sales reps based on early numbers, or redeploy a sales team from one city to another to take advantage of current market conditions.

From a long term standpoint, the owner company also benefits from being able to establish their own roots in the community under the tutelage of the commercial solution provider team. Unlike other partnership models, in this scenario, the product owner can opt to eventually take over the sales process, moving headcount onto their own books, and proceeding forward with the market process entirely under their own banner. This gives them the long term strategic advantage of going it alone while avoiding short term mistakes, and ensures they never have to give up control of that products market destiny. *In short, this final option can offer speed, flexibility and risk mitigation, not to mention enhanced control.*

> Partnering with a commercial solutions provider can offer small and midsized companies many of the early benefits of partnering with big pharma or a distributor, as well as the long term benefits of going it alone.

Figure 2 – Components of a market entry solution

Legal entity			
Medical/Regulatory	**Commercialization**	**Supply & distribution**	**Quality, governance and compliance**
Dossier preparation Agency interaction	Brand management	Importation	Integrated compliance approach
Clinical trials	Market access Value dossier	Warehousing	
Medical information and pharmacovigilance	Managed markets Contracting	Distribution	
Patient support	Market research		
Medical communications	Commercial analytics		
Medical science liaisons	Field force operations		

How to choose

There are many factors to consider when developing an emerging market entry plan, and business leaders want to be sure they have looked at all of the short and long term benefits and risks before making a decision. When companies take the time to build a solid business plan, and consider how the choices they make today will align with their current access to capital, individual product goals and long term strategic expectations, they will make the best decision for the product, the portfolio and their own bottom line.

References

1. http://www.bloomberg.com/news/2013-09-03/china-catastrophe-hits-114-million-as-diabetes-spreads.html
2. http://www.pmlive.com/pharma_intelligence/the_rise_of_chronic_disease_in_bric_markets_487936
3. http://www.pmlive.com/pharma_intelligence/the_rise_of_chronic_disease_in_bric_markets_487936

Contact us

Toll free: 1 866 267 4479
Direct: +1 973 850 7571
Website: www.quintiles.com
Email: commercial@quintiles.com

QUINTILES®