

ASIA MARKET ENTRY

Opportunities & Challenges

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ASIA

A continent of extremes, with great potential for growth

Asia is a continent of diversity. Geographically large, the assortment of cultures, people, disease profiles, and healthcare systems added to the juxtaposition of extreme wealth and extreme poverty, emphasises the many challenges faced by the pharmaceutical companies when thinking of entering Asia. Countries such as Russia, India and China have traditionally been considered the key players in emerging markets.

However, vigorous economic growth, government healthcare reforms, population growth, increasing per capita income and changing disease profiles have led to a greater demand for healthcare and pharmaceuticals across other markets in the continent - nowhere more so than the 10 countries that comprise the Association of Southeast Asian Nations (ASEAN) - Indonesia, Malaysia, Philippines, Singapore, Thailand, Brunei, Myanmar, Cambodia, Laos, and Vietnam.

The ASEAN countries have a combined population of more than 625 million, nearly double that of the United States and more than 120 million higher than that of the EU. Topping \$2.3 trillion, with a GDP per capita of US\$3,748, their combined GDP is equal to around one-quarter that of China, and the region saw GDP growth of about 7% in 2013, compared with negative growth in the EU and approximately 2% growth in the United States¹.

This opens a huge opportunity for pharmaceutical companies, amidst increasingly complex and evolving healthcare systems. Commercial success will depend on understanding the market dynamics by consolidating positioning within the market place with the requirements of each market.

¹ <http://www.mddionline.com/article/asean-countries-could-be-next-emerging-medtech-markets>

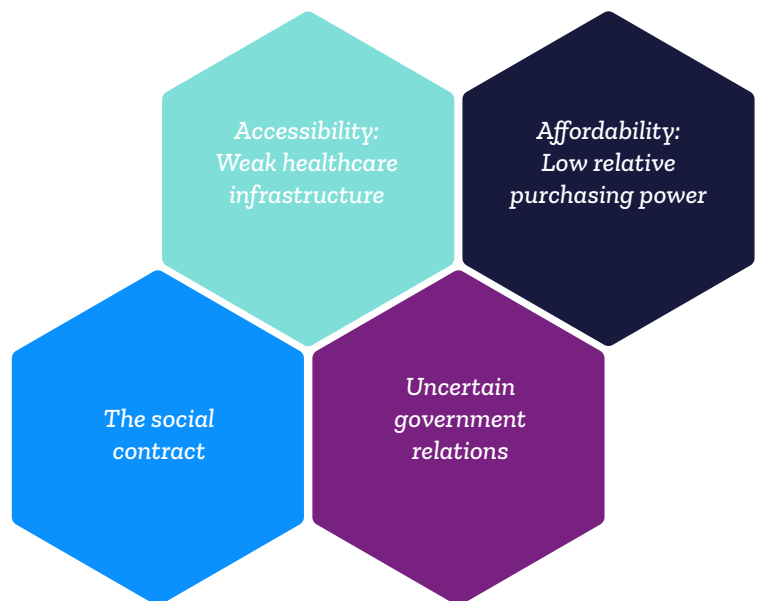
New markets that require a bespoke business approach

Due to their complexity, the emerging markets within Asia should be considered as 'New Markets' that require a bespoke business approach

Given the potential available within the emerging markets in Asia, these markets are becoming very attractive to those companies suffering from the stagnation of mature markets, patent expirations, and increased regulatory hurdles, and are anticipated to play a vital role in sustaining growth for the pharmaceutical industry. However, although these markets offer huge untapped potential, they display a wide diversity in their stages of development, particularly with regard to their healthcare infrastructure. For this reason, there can be no "one-size-fits-all" approach to emerging Asian markets. The local idiosyncrasies make bespoke approaches to these markets even more essential.

The complexity across the region can be summed up into four main areas, accessibility, affordability, government relations and the social contract or social expectation. To access patients and consumers requires companies to understand and support coordinated efforts to create or strengthen the healthcare infrastructure, increasing access. The geographical split between rural to urban areas, the diversity in linguistic requirements and the inequalities in wealth distribution all contribute to the complexity of navigating the requirements across the region. Understanding true patient needs and implementing an agile and flexible supply chain will be critical in building an effective supply chain that serves the needs of the local market. Looking across the industry the top multinational (MNC) pharmaceutical companies have ranged in their success in emerging markets, but what is clear, is that there is a clear and robust correlation between business performance across the region and formulation of a proactive and tailored "access" strategy.²

The complexities of emerging markets



Within the emerging markets in Asia, the potential for large sales volume is tempered by lower purchasing power. The acute price sensitivity imposed as a result of patients not being able to support prices comparable to developed countries leaves pharmaceutical companies in a dilemma on whether to adopt tiered pricing models which could ultimately result in eroding margins in other markets.

In a landscape where the greatest number of potential patients reside at the bottom of the pyramid (lower income to lower middle income sector), a strategy in which volume over price margins takes precedent will be key in establishing a mid to long term strategy by establishing a strong patient base within growing markets where purchasing power is likely to increase over time.

The nature of the relationship between the MNCs with branded products and governments is also significantly different in emerging markets from the one in mature markets. Constantly evolving healthcare regulations and policies together with unpredictable business environments and a propensity to encourage cheaper domestic generic players can leave multinational pharmaceutical companies in a tricky situation.

However, with an increasing drive towards harmonisation of regulations between the mature markets and the emerging markets, there is a drive to establish more transparent policies easing tensions between government and big pharma.

² Access to Medicines: The Next Frontier, Accenture, 2014



The expectation that manufacturers of life-saving products make them available to the people who need them most is one characteristic of the unique 'social contract' between the pharma industry and the wider society. This is particularly important in markets with weak government health provisions (e.g. India, China, Myanmar, Cambodia, Laos, and Vietnam) where the private sector has stepped in to solve the public sector problems. How precisely to manage this situation is unclear and questions remain on how society can be persuaded of the value of a company's involvement in the economy of the society and whether this should be a joint venture leveraging the local strength of generics players together with the experience of global pharma.



*"In the midst of chaos,
there is also opportunity"*

Sun Tzu

Choose your battles wisely

Author of *The Art of War*, an ancient Chinese military treatise, Sun Tzu was a high-ranking military general, strategist and tactician. We incorporate many of Sun Tzu's ideas and ideals in our lives every day without knowing it, not because we have studied him or are his followers, but because it makes sense.

His belief that "In the midst of chaos, there is also opportunity", seems particularly pertinent here. Because, although on the whole, these complexities pose challenges to pharmaceutical companies looking to venture into and capture the new emerging markets of Asia, there are considerations that can be factored into planning which will help navigate the multifaceted dynamics, some of which are considered below.

The strategy will need to be tailored and adapted for high growth, high revenue markets (e.g. China, India) as compared to high growth, low margin markets (e.g. ASEAN markets), but the process of navigating the complexities remains consistent.



Market entry considerations

A robust market strategy must take into account all factors affecting the market's true potential

Despite the challenges and differences highlighted, devising a tailored, step-wise market entry strategy fulfilling the needs and requirements of the local market will be key in establishing a successful legacy across the region.

Market entry considerations



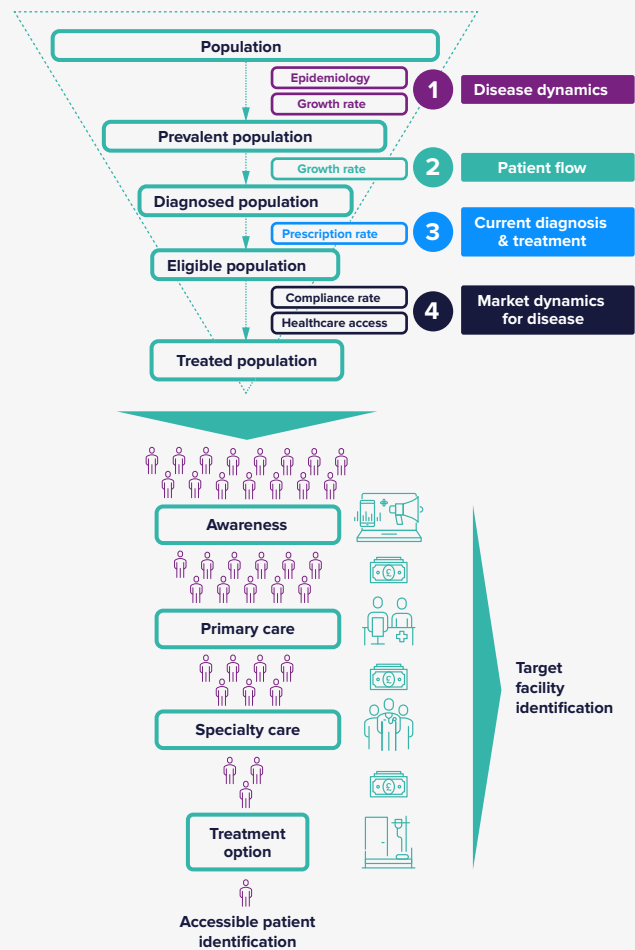
Patient population dynamics

Multiple angles should be evaluated when considering the eligible and accessible patient populations accurately. Establishing patient epidemiology (total and eligible patients) and its growth rate will define the total market potential in terms of maximum achievable number of doses sold. Assessing the disease state, current treatment options, medical unmet need, treatment protocols and existing local practice will help build an overview of the local market dynamics.

The complexity of obtaining epidemiological data for the emerging markets of Asia varies depending on the market and the therapy area/disease under consideration. While the resources and databases (IMS, NIH, SEER, etc.) commonly used to gather such data for western markets are growing in scope to include the larger markets within Asia (e.g. China, India); there is less information available for the ASEAN markets.

Evaluating the patient population dynamics and ascertaining the true market potential for such countries therefore requires a process of triangulation leveraging available data, utilising in house expertise and knowledge about market specific dynamics and validating with KOL experts.

Understanding patient population dynamics



Healthcare landscape

Stakeholder identification is essential to understand whom to approach in order to have products listed in formularies. Given the market specific differences across Asia it is essential the key healthcare facilities are identified, the stakeholders and decision making process is mapped out specific to each indication or therapy area and market, helping develop tailored strategies. For instance while the majority of patients suffering from major depressive disorder (MDD) are diagnosed by and treated by psychiatrists in Hong Kong, in South Korea general practitioners play a big role in terms of repeat prescriptions. Knowledge of the market specific nuances will be key in identifying the target stakeholder group and tapping into the true potential.

Product registration and launch

Product registration timeline and process must be established in order to determine the point at which sales can start and revenue can be generated.

Unlike Europe, a central regulatory agency such as the EMA (European Medicines Agency) does not exist across Asia. Though there are efforts to harmonise the regulations across the region, these are seen as ongoing with no clear deadline of when the regulations may come to fruition. For instance, even though most markets across the ASEAN countries have adopted the ACTD/ACTR, the Philippines is still lagging behind resulting in different requirements for product registration. A cohesive registration process for orphan drugs across these markets is not yet established, with lack of transparency further undermining the registration process. Up to date knowledge of the evolving regulatory landscape through local language interviews with key stakeholders to understand the dynamic landscape (current and future), and the country specific requirements for different indications will be key in establishing bespoke regulatory insights for each market under consideration.

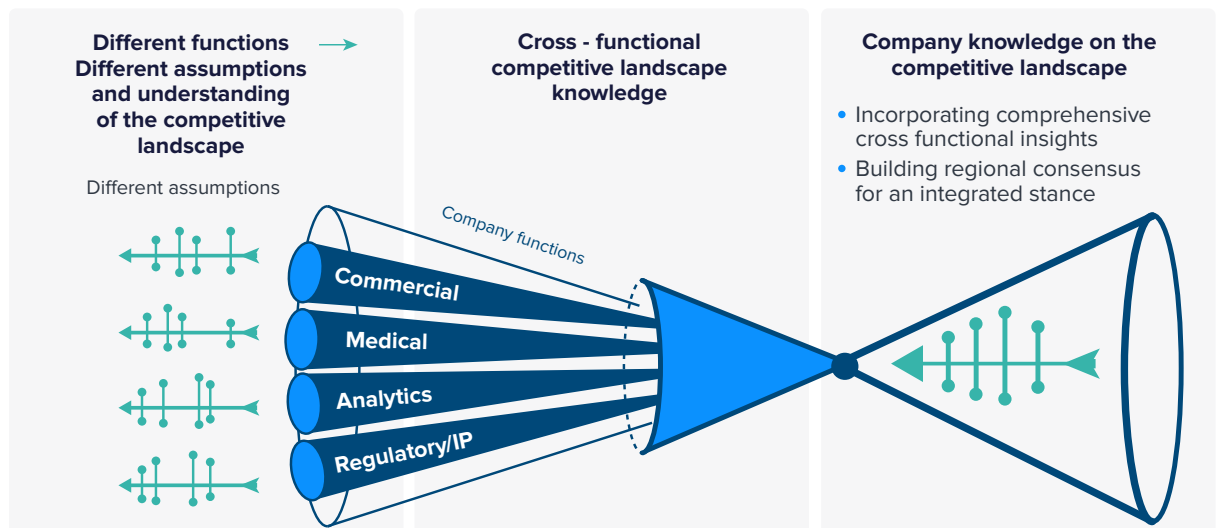
Competitor landscape

Understanding the competitor's launch dates and strategy, competitor sales and marketing capabilities, competitor positioning and messaging, market access strategy, plan for life cycle management will be key in planning the best strategy for market entry and devising an effective counter-strategy. Utilising competitor intelligence that provides high value insights, leading to actionable recommendations will help support commercial and corporate decision making when considering market expansion.

Gaining competitor information in Asia can prove more difficult depending on the market of interest. Pharmaceutical MNCs often outline and share their strategy and plans for the US and EU much more clearly than they do for Asia and in particular the emerging markets of Asia.

Annual company reports, quarterly company reports, press releases, IMS data and a more active presence at global conferences allow for the easier collection of such insights in the EU and US. In the smaller emerging markets of Asia however, an understanding of the local competitor dynamics along with local language capabilities will be key in establishing competitor insights through a triangulation process; whereby information available through secondary sources (often in the local language) is supplemented with internal expertise and validated with insights gathered through primary interviews with analysts, company sources, KOLs and experts (often conducted in local language).

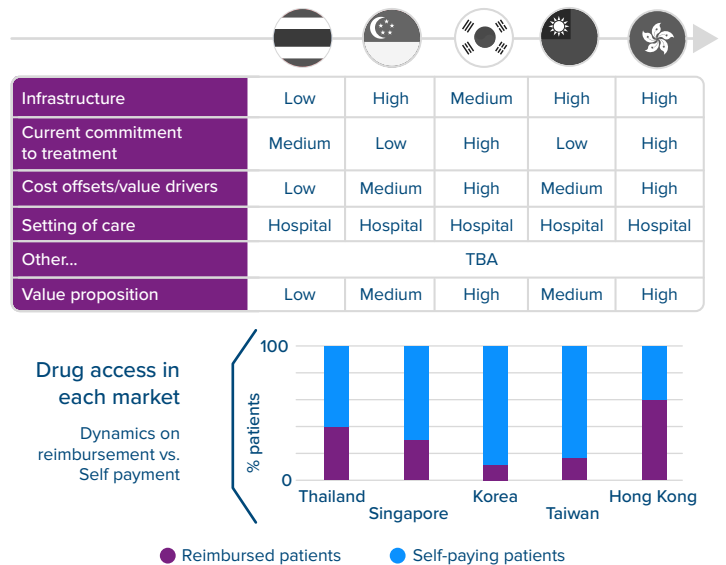
Establishing a unified notion of the competitor landscape



Pricing and market access

From a company perspective, price and market access are highly influential factors in determining product revenues. The ultimate goal is to achieve market access for a new product at the optimal price, within the shortest time. When formulating a strategy for emerging markets, however there has to be a shift in thinking. High pricing margins can alienate governments and limit access and uptake to a subsection of the population. A flexible pricing strategy built on the ethos of volume over price may feel uncomfortable, but ultimately could be the best suited strategy depending on the market under consideration. A product's value proposition must consider price (affordability) as well as accessibility.

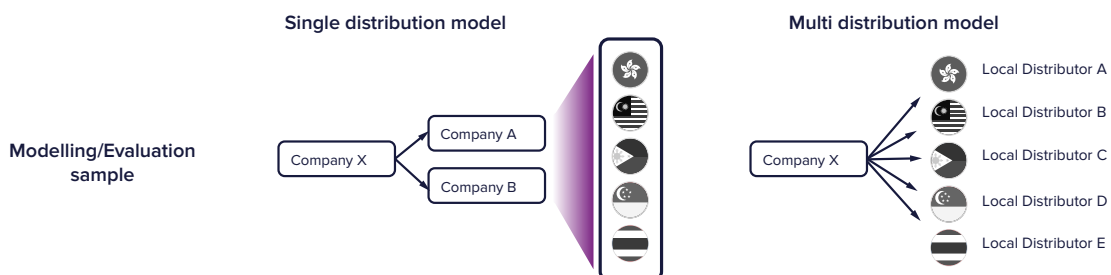
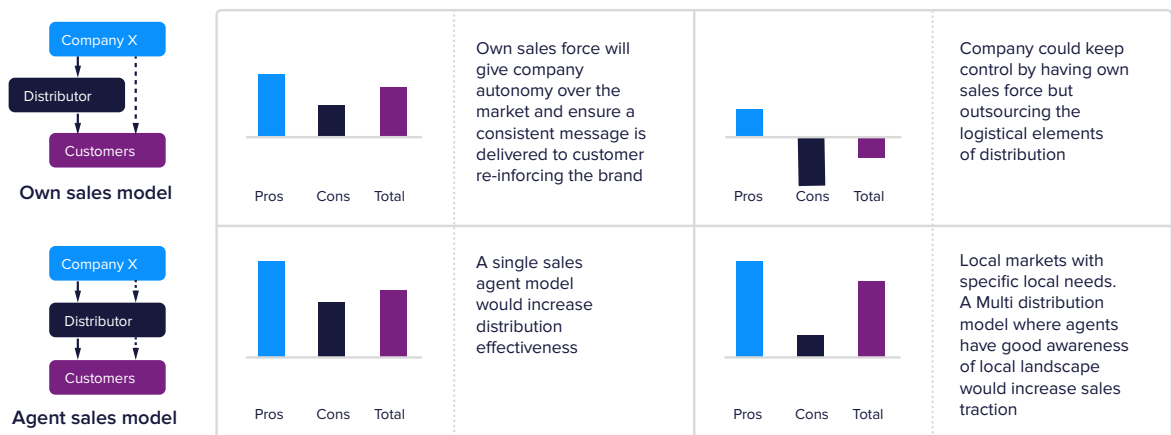
Payer landscape and payer sensitivity



Payer considerations (illustrative)

Commercial operation strategy

For multinationals with limited presence and market knowledge in the emerging markets of Asia, companies need to explore the optimal strategy for their market entry and commercialization model in the region; one which offers the greatest return on investment. Identification of the most effective sales model; direct sales force vs. distributor model vs partner; establishing the optimal supply chain program; competitor commercial and medical field force benchmarking to refine internal field force organization and deployment strategy are all key in establishing an effective commercial operational strategy for entry into emerging markets.



Elements of commercialization strategy for consideration

About the Author

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Anousha is a Senior Consultant based at the Deallus Singapore office. Anousha offers broad experience across both the medical device and pharmaceutical industries.



Her areas of expertise include strategic and operational leadership in market entry, market analytics, pricing and reimbursement, regulatory (FDA, EMA, CFDA) and compliance systems for medical devices including drug-device combination products and pharmaceuticals.

About Deallus

Deallus is a unique strategic intelligence consultancy operating across the global life sciences sector.

Our mission is simple: to prepare you for the future by delivering the forward-thinking assurance you need in an uncertain and highly competitive world.

The knowledge and clarity we provide helps life sciences companies shape future markets by making the right strategic decisions with confidence.

Conclusion

Emerging markets of Asia represent a significant growth opportunity for the pharmaceutical sector. Due to their complexity, emerging markets of Asia should be considered as 'New Markets' that require a bespoke business approach taking into account the multifaceted nature of the markets.

Understanding the complexities of each market will support the formulation of an effective entry strategy specific to each market.





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