Roland Berger
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Saudi Arabian pharmaceuticals

Will domestic players be able to adapt to the industry's changing landscape?

Roland Berger Turkey, Middle East & Africa

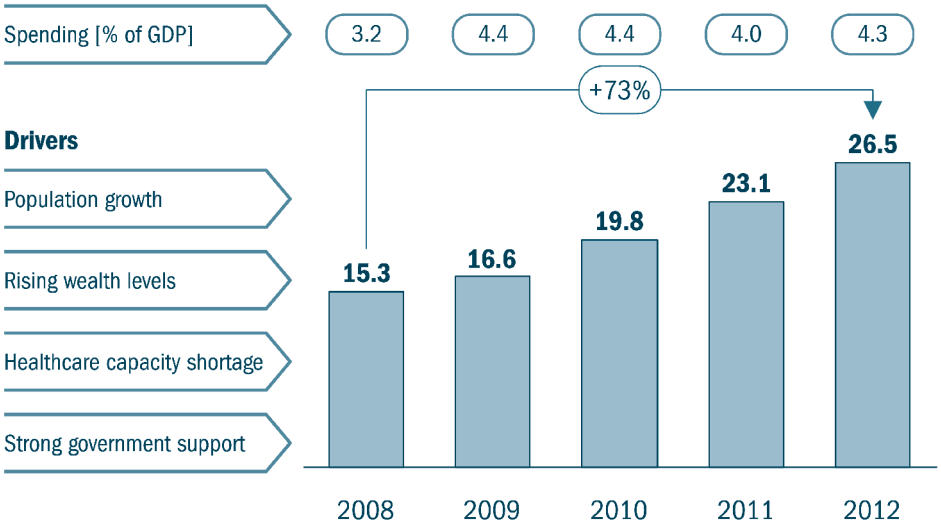
Saudi Arabian pharma market: Redefinition of the competitive landscape

While most of the developed world is facing economic uncertainty, Saudi Arabia's economy has been flourishing driven by ambitious economic diversification initiatives, strong oil prices and record-high fiscal budgets. As a result, the country's GDP has steadily grown over recent years, recording high single-digit growth rates and resulting in USD 700 bn in 2012.

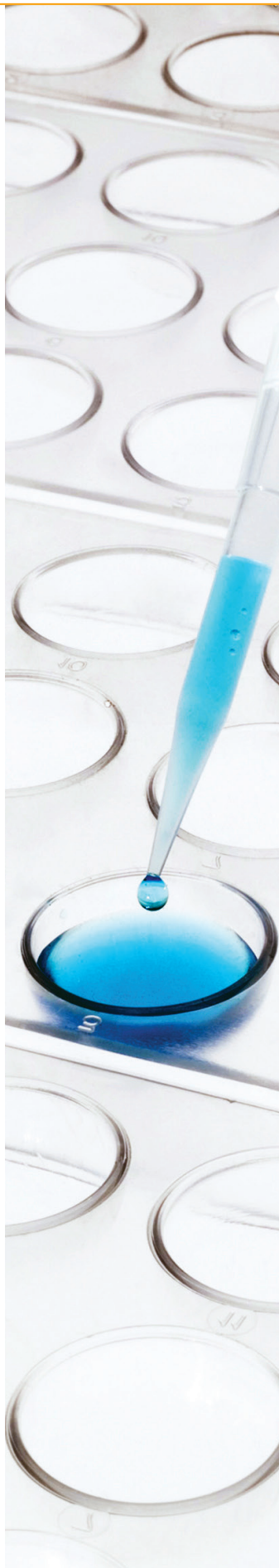
The robust growth of Saudi Arabia's economy has been coupled with a rapidly growing population fueled by a strong influx of expatriates. With a population growth rate exceeding 2% p.a., Saudi Arabia's healthcare budget as a percentage of its GDP has increased from 3.2% to 4.3% over the period 2008 to 2012. Underpinned by solid healthcare demand fundamentals, the pharmaceutical industry has consequently grown in the same time from USD 3.0 bn to USD 3.8 bn. This growth was also supported by several key demand determinants including rising wealth levels, increased private consumption of medicines, improved longevity and a growing number of chronic diseases such as diabetes and gastrointestinal disorders.

The pharmaceutical sector is expected to maintain its strong growth momentum however a gradual shift towards low-cost generics coupled with a stronger market penetration of global pharma players might lead to a redefinition of the competitive landscape. One probable outcome may yield a bi-polar market dominated by branded patented drugs on one hand and low-cost generics on the other. As a result, domestic players may end up squeezed in the middle having a diluted value proposition with only the fittest surviving the race.

FIGURE 1: DEVELOPMENT OF HEALTHCARE SPENDING IN SAUDI ARABIA [USD bn]



Source: Roland Berger analysis, WHO

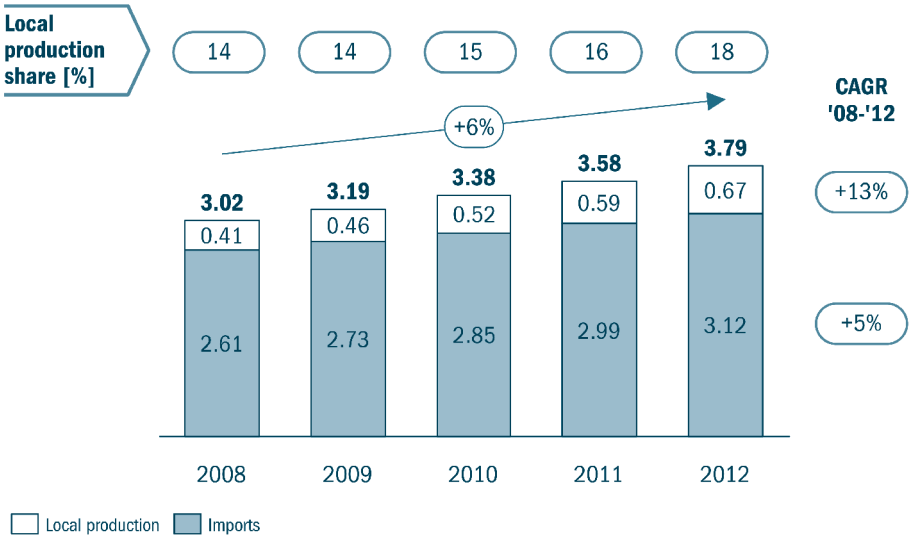


Local players: A core element of the Saudi pharma formula

Over the past couple of decades, domestic players have come a long way to becoming a core element of the Saudi pharmaceutical market formula. Starting as sole importers and distributors of pharmaceutical products, companies such as Banaja Saudi Import Company, Spimaco, Tabuk Pharmaceutical Manufacturing and Al-Jazeera Pharmaceutical Industries gradually developed their capabilities, ultimately establishing fully-fledged local manufacturing facilities. In addition, several domestic players created partnerships and joint ventures with global and regional pharma players lured by various government-sponsored incentive schemes aimed at promoting local manufacturing.

As a result, there are currently 27 pharmaceutical manufacturers operating across the Kingdom accounting for around 18% of the market's value. Despite representing a relatively small share of the market, local production has recently picked up momentum increasing from 14% to 18% of the total market value over the period 2008-2012.

FIGURE 2: DEVELOPMENT OF THE PHARMACEUTICALS MARKET IN SAUDI ARABIA [USD bn]



Domestic players are mostly focused on branded generics manufacturing, i.e. off-patent prescription market. Some of them are also handling contract manufacturing opportunities under license agreements with international players Pfizer, GSK and J&J.

While the Government is actively supporting the growth of local value chains by encouraging joint ventures and sponsoring non-tariff barriers in the form of price control mechanisms, domestic players face two main imminent challenges:

1. Muscling in of global pharma giants into Saudi Arabia
2. Expected rise in popularity of generics produced in low-cost countries

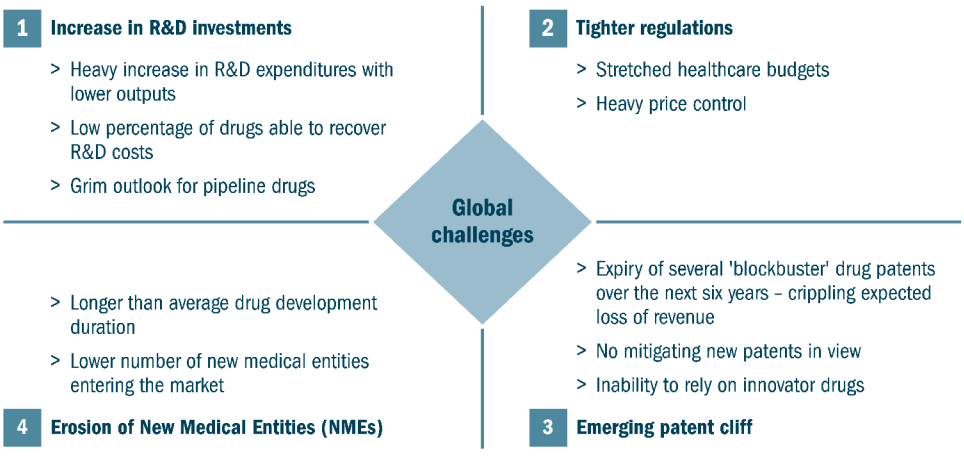
Global giants muscling into Saudi Arabia: Increased focus on pharma's "promised land"

For many executives of global pharmaceutical companies, mature markets have lost much of their appeal due to the difficulty of establishing a competitive edge. In fact, mature markets are expected to stagnate in the near future and global players are facing many challenges in this regard.

From a regulatory perspective, tight healthcare budgets resulted in heavy cost-benefit scrutiny for in-market products. Despite increasing R&D investments, an 80% rise over the past decade, the number of new medical entities (NMEs) has fallen by 43% over the same period. This radical decrease in NMEs is primarily due to more complex study requirements, extending the development period of new drugs by approximately 30%. As a consequence, only three in ten marketed drugs produce revenues that match or exceed the average R&D costs. The outlook is even grimmer for pipeline drugs: only one in eight approved compounds is expected to generate returns that are in line with their communicated targets.

Moreover, it is foreseen that several 'blockbuster' drug patents will globally expire during the next six years, putting over USD 200 bn of sales at risk for pharmaceutical giants. Such a loss of exclusivity, known as the patent cliff, coupled with no mitigating new patents significantly weakens the position of pharmaceutical manufacturers primarily reliant on innovator drugs.

FIGURE 3: CHALLENGES FACED BY PHARMACEUTICAL COMPANIES IN MATURE MARKETS



Manufacturers are therefore left in a position whereby top-line optimization is of fundamental importance, forcing many to turn to emerging markets for solutions. The shifting focus of big pharma players is already evident: they have started to build and enlarge their footprint in emerging countries – regarded as the “promised land” – as these markets offer a potential solution to their strategic dilemma.

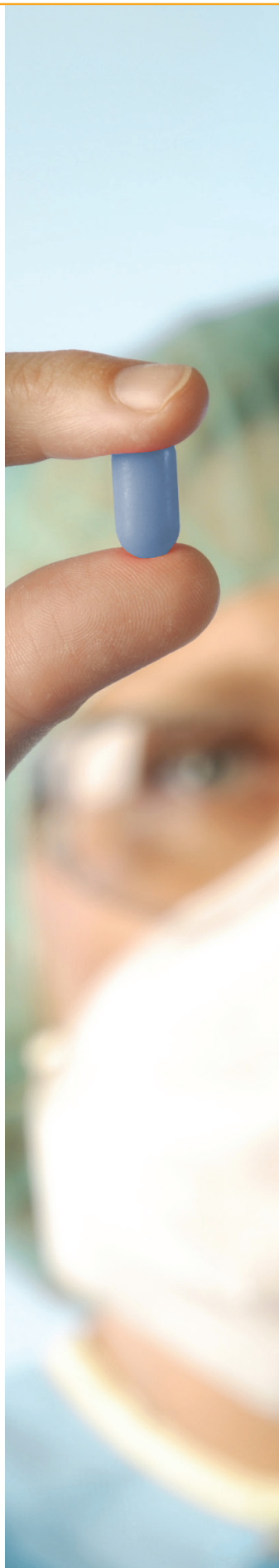
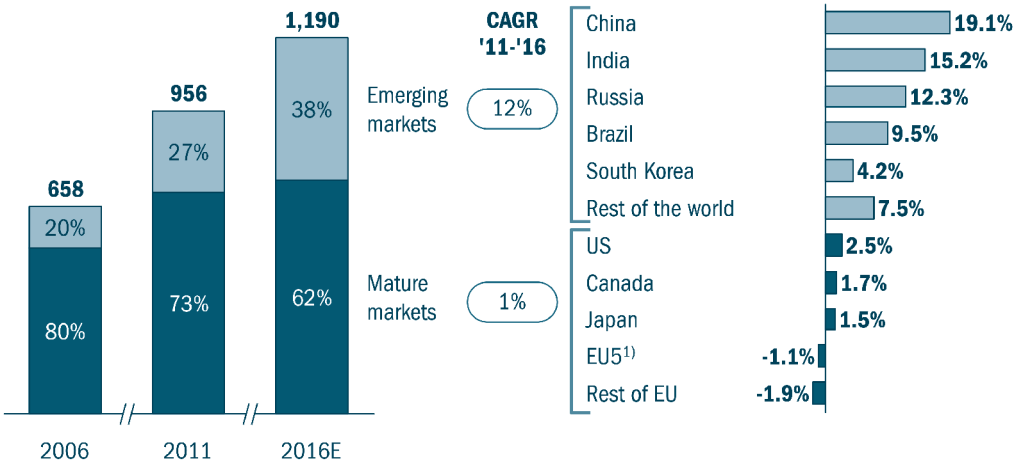


FIGURE 4: GLOBAL PHARMACEUTICALS REVENUE BREAKDOWN AND GROWTH [USD bn]



1) EU5 includes Germany, France, Italy, Spain and UK
Source: Roland Berger analysis, IMS Institute for Healthcare Informatics 2012

In this context, Saudi Arabia offers significant potential. Underlying the interest of big pharma in the Kingdom is a strong consumer preference for branded drugs. Today, branded pharmaceutical products account for around 80% of the total pharmaceutical sales in Saudi Arabia.

Nevertheless, a key issue facing global pharmaceutical exporters to Saudi Arabia are the regulatory obstacles imposed by Saudi authorities attempting to protect local manufacturing. These include protracted registration procedures for foreign drugs, requirements for re-certification and stringent price control mechanisms on certain drugs. As a result, global pharma giants have to date only established limited direct presence in Saudi Arabia in the form of joint ventures with local firms. In fact, most international companies still favor market access through trade or licensing-out agreements mainly because of intellectual property concerns and regulations favoring domestic players.

The establishment and proliferation of multiple free-zones across the Kingdom however has allowed foreign players to establish 100% foreign-owned operations and is expected to position Saudi Arabia as a pharmaceuticals manufacturing hotspot capable of luring global giants. In this respect, King Abdullah Economic City (KAEC) has already attracted the attention of big pharma players, e.g. Sanofi-Aventis and Pfizer, leading to agreements for the setup of manufacturing facilities in Saudi Arabia. The entrance of players in the Saudi Arabian market will alter the competitive landscape for existing domestic manufacturers and indirectly alleviate cumbersome regulatory pressures thereby yielding a level playing field. Furthermore, new entrants will benefit from their increased proximity to the market and hence become more competitive. In the context of public procurement, local players will undoubtedly benefit from increased exposure to public tenders and will be able to adapt quicker than their distant counterparts to what is essentially a dynamic competitive process. In the private sector, big pharma will be able to keep a closer watch on activities further down the value chain for which they depend on local collaboration with established market ties.

Once established in the Kingdom, international companies will jeopardize a core component of the operations of local players as a number of licensing and contract manufacturing agreements become redundant. This will manifest itself in the form of reduced reliance on local producers for the import of branded pharmaceuticals.

FIGURE 5: SELECTED MARKET ENTRY EXAMPLES OF GLOBAL PHARMA INTO KSA

Company	Location	Key information
GlaxoSmithKline	Jeddah	> Joint venture with Banaja Holdings - Glaxo Saudi Arabia Limited > 75,000-square-meter facility with a yearly production capacity of 12 million tubes, 3.5 million bottles, 4 million inhalers and 15 million tablet packs > Produced drugs include Glaxo's anti-ulcerant Zantac and its anti-asthmatic Ventolin
astellas / Daiichi-Sankyo	Jeddah	> Joint venture with Tamer - SAJA > 30,000-square-meter facility producing Sankyo and Yamanouchi products as well as contract bulk production for other Japanese drug companies
Pfizer	King Abdullah Economic City, Rabigh	> 32,000-square-meter planned facility with a yearly production capacity of 18 million packs > Planned packaging and warehousing of several Pfizer solid dose medicines currently supplied to the KSA market
sanofi aventis	King Abdullah Economic City, Rabigh	> 35,000-square-meter facility with planned production spanning up to 20 products including oral anti-diabetics and cardiovascular drugs > Research activities to be conducted in coordination with KAUST

The rise of low-cost generics

The development of innovative drugs has historically been the cornerstone of major pharmaceutical companies worldwide, requiring established research and development facilities as well as a mature legal environment capable of safeguarding intellectual property. As a result, pharmaceutical companies have experienced periods of protected innovation during which a product line prospers in the market and safeguards return on investments.

Tightening healthcare budgets however are challenging the dominance of large pharmaceutical companies and leading to a rise in low-cost generic alternatives. In an effort to curb the exploding cost of healthcare provision, govwernments in both developed and emerging markets are seeking to contain spending on pharmaceuticals.

The aforementioned patent cliff has resulted in the commoditization of pharmaceuticals once priced at a premium. Consequently, a switch to low-cost generics is a natural step for

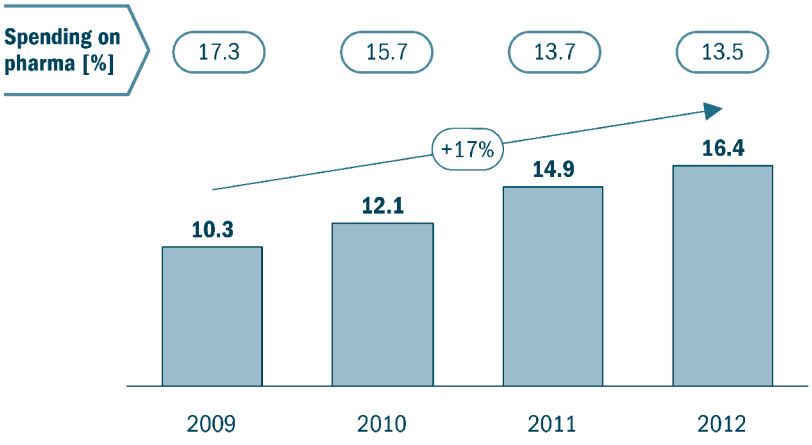
many governments seeking to implement cost-optimization initiatives and promote efficient healthcare expenditure. For example in Italy, physicians prescribing patented drugs are now obliged to indicate whether the drug can be substituted by an effectively equivalent generic alternative. As a result, generic drugs are expected to grow at a solid CAGR of approximately 12% accounting for 25% of the global pharmaceuticals market in 2014.

Crucially, the continued gradual loss of exclusivity facing Big Pharma will allow competitively-priced generics to be manufactured in low-cost countries (LCCs), such as India and China, leveraging their substantial manufacturing resources and economies of scale. Manufacturers in LCCs are preparing for the impending generics boom and expanding their operations through acquisitions and major capacity additions.

Saudi Arabia will also be affected by the rise of generics. As of today, generic drugs account for less than 20% of the pharmaceuticals market. Nonetheless, several factors, mostly notably the increasing need to curtail spending on pharmaceutical products as the Kingdom transitions towards a market-driven model, will contribute to the growth of generics in both the public and private sectors.

Despite Saudi Arabia's increased overall public spending on healthcare, a staggering CAGR of 17% over the period 2009-2012, the government has succeeded in reigning in its pharma expenditure as a percentage of the total healthcare spending, decreasing from 17.3% in 2009 to 13.5% in 2012.

FIGURE 6: SAUDI ARABIAN PUBLIC SECTOR SPENDING ON HEALTHCARE [USD bn]



Source: Roland Berger analysis, NCB

The curtailing of pharmaceutical expenditure was achieved through the adoption of several measures including the introduction of regulations aimed at promoting/favoring local production, the establishment of a national Pharmacoeconomic Research Center and the setting-up of the National Unified Procurement Company for Medical Supplies (NUPCO). This has allowed the government to channel healthcare funds towards front-line operations such as addressing bed capacity shortages across the Kingdom.

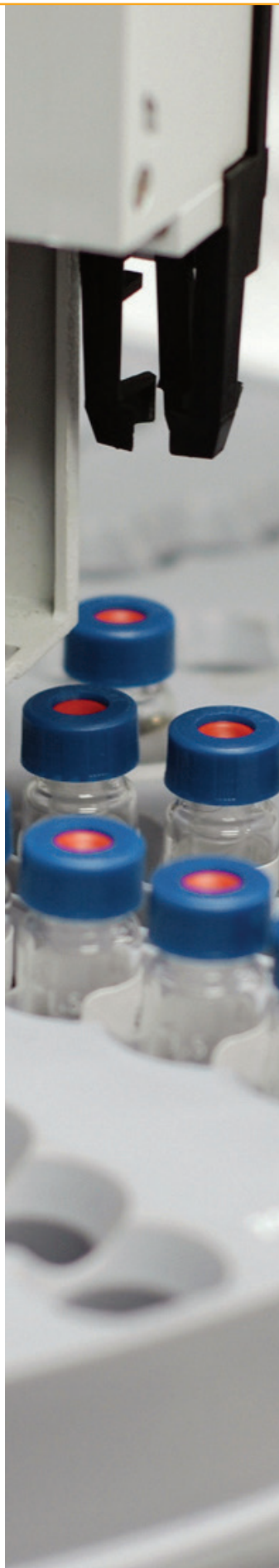
FIGURE 7: KEY GOVERNMENT MEASURES FOR CURTAILING PHARMA EXPENDITURES

Regulatory measures	Pharmacoeconomic Research Center	National Unified Procurement Company for Medical Supplies (NUPCO)
> Implement guidelines for the promotion of local production	> Identify, measure and compare pharmaceuticals costs and outcomes	> Handle government tenders
> Establish a mandatory personal insurance plan for individuals in KSA	> Allow efficient allocation of healthcare assets within constrained budget	> Facilitate procurement, storage and distribution of medical supplies
> Establish and monitor a tight pricing control favorable for local players	> Guide and monitor the cost-effectiveness usage of pharmaceuticals healthcare professionals and patients alike	> Allow bundled procurement thereby achieving operational efficiency, inventory effectiveness and economies of scale

It is expected that NUPCO will follow other government entities in adopting policies favoring domestic production companies. However, given its primary mandate of low-cost procurement, it is not clear if its establishment will support homegrown pharmaceuticals in the long-term. The sheer scale of NUPCO's operations coupled with its growing bargaining power with suppliers could negatively impact the profitability of domestic branded generics manufacturers unable to compete with LCC pharmaceutical giants in terms of volume and price. Four years after the establishment of NUPCO, the Kingdom's existing medical import and distribution firms are already complaining that NUPCO is negatively impacting their business as they are unable to compete on scale.

Moreover, the penetration of private health insurance will play in the favor of generics as insured expatriates, and eventually Saudi nationals, are channeled towards private hospitals and healthcare facilities. In the short-term, this trend will serve the interests of domestic manufacturers as their product offering primarily focuses on branded generics.

Nevertheless, once insurance providers secure a strong foothold in the market, their increased leverage over healthcare providers will allow them to drive private healthcare prescriptions towards cheaper forms of generics manufactured in low-cost countries, as is already the case in several developed markets.



Aside from the regulatory hurdles facing foreign imports (in terms of approval, etc.), the Saudi Arabian government is currently able to stifle competition from LCC pharmaceuticals through tight pricing controls which fix relatively low retail prices for imported products preceded by domestic counterparts. Given the legally established fixed profit margins for Saudi Arabian wholesalers and retailers, overseas suppliers wishing to enter the Saudi market are forced to cut their prices, effectively single-handedly bearing the financial burden of entering the Kingdom.

Yet, the efficacy of such pricing controls is tightly linked to current demand patterns – any change from the status quo will considerably alter market dynamics. Thus, it is important to note that the trend towards low-cost generics will prevail even with the price control mechanisms currently shielding domestic players from LCC manufacturers. The forecast avalanche of demand for low-cost generics – both from increased insurance penetration and anticipated public procurement tenders via NUPCO – will compensate for the lower margins of LCC manufacturers, adding further pressure on domestic players. Any future softening of protectionist policies (for example, as a result of the Kingdom striving for full compliance with its 2005 WTO accession) will however leave domestic manufacturers stranded, competing head to head with generics heavyweights who enjoy a dramatically lower cost-base and optimized operations.

Existing operating models for established local pharma players might be jeopardized in the near future – How to leverage the status quo and ensure long-term success?

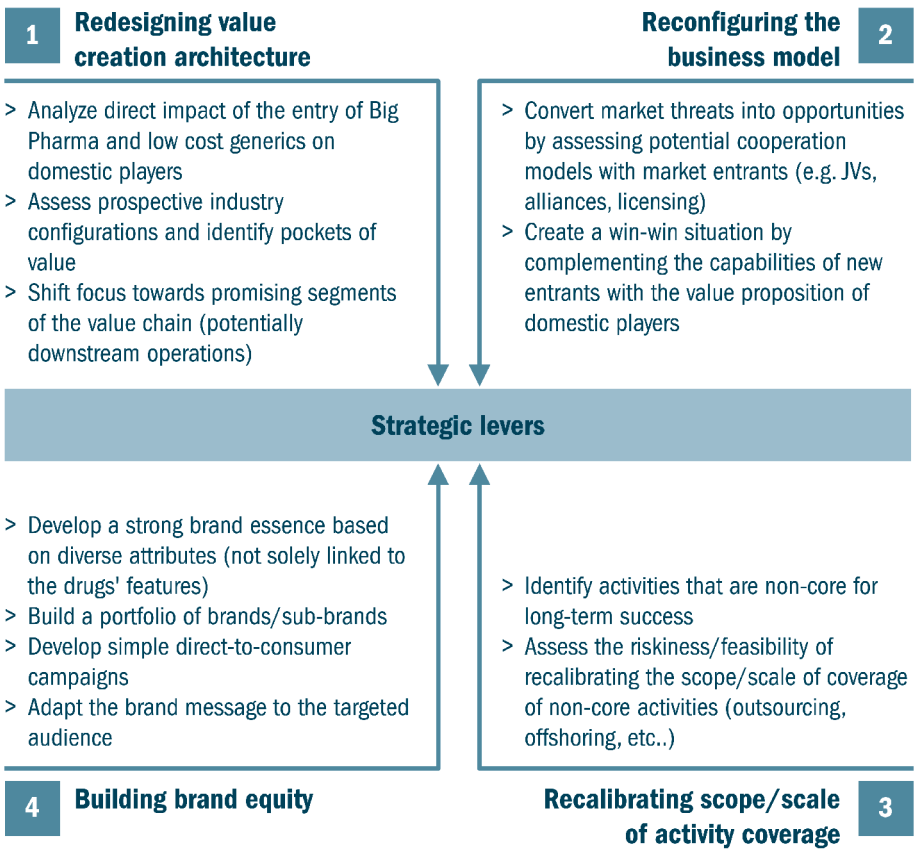
The increasing pressure exerted from the entrance of global pharma giants into the Saudi market, coupled with the government's agenda to regulate and push for low-cost generics will change the face of Saudi pharma in the future and force local players to find answers to several crucial questions:

- How should players position themselves along the value chain (e.g. development, production, marketing, sales, distribution, retailing)?
- How should companies optimize their business model in preparation for the entry of Big Pharma into the Saudi market? How should they leverage their in-depth knowledge of the Saudi market and in turn ensure their survival and prosperity?
- What is the best approach to optimize operational efficiency (e.g. strategic sourcing strategy, inventory management, logistics)? Which activities (core vs. non-core) should be kept in-house and which should be outsourced/offshored?
- What is the value proposition provided by players? Which brand strategy should be adopted to create "local champions" in order to maximize returns?

Domestic players: A changing environment requires the orchestration of a multitude of strategic levers

In order to address the potential challenges posed by the penetration of global pharma players and low-cost generics, domestic players need to orchestrate a multitude of key strategic levers to sustain a competitive value proposition.

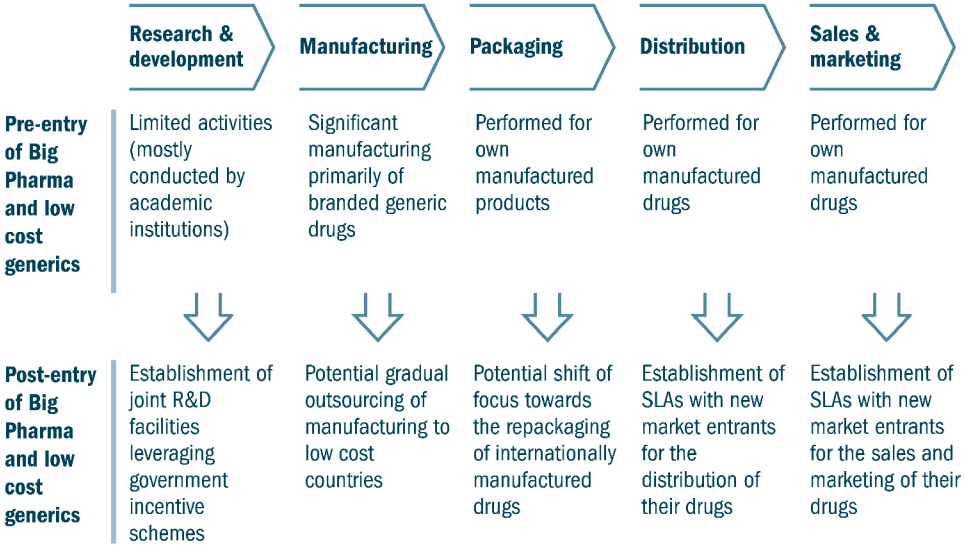
FIGURE 8: KEY STRATEGIC LEVERS FOR SUSTAINING A COMPETITIVE VALUE PROPOSITION



Redesigning value creation architecture

Being squeezed on the top-line – mainly by locally produced branded generics of Big Pharma – and on the bottom-line – mainly by pure generics of volume-focused and low-cost competitors – will require a re-evaluation and adjustment of the entire business and value creation architecture. Manufacturing might not be the core business for domestic players in the future. For example, by outsourcing production to LCCs, the in-country operations of Saudi players could solely focus on repackaging. Also, domestic players should make use of their deep knowledge and understanding of the market as well as of the favorable regulatory situation - granting them exclusivity in most downstream segments of the value chain - to tighten their grip over the marketing, sales and distribution activities of the industry.

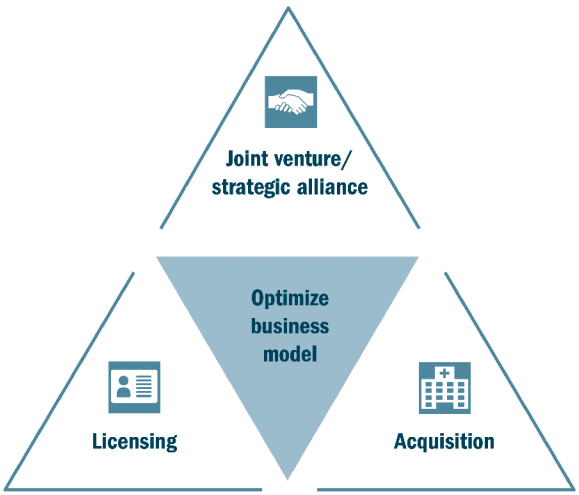
FIGURE 9: POTENTIAL EVOLUTION OF VALUE CHAIN COVERAGE OF LOCAL PHARMA PLAYERS



Reconfiguring the business model

Domestic players need to turn potential market challenges (resulting from the penetration of Big Pharma players) into opportunities by actively pursuing mutually beneficial partnerships. Domestic players possess superior knowledge and influence in the local market, mainly through their solid understanding of the local market dynamics, long-term connections with the authorities and strong relationships with key stakeholders. On the other hand, Big Pharma players have an edge mainly through their deep technical know-how, advanced R&D capabilities, strong brand equity as well as economies of scale. By complementing the capabilities of international players with the value proposition of domestic players through joint ventures, strategic alliances or in-licensing agreements, a win-win situation could be created, turning a potentially challenging scenario into an attractive business opportunity.

FIGURE 10: POTENTIAL BUSINESS MODELS – PROS AND CONS



Joint venture/ strategic alliance

Team up with established pharma player(s) in the Saudi market:

- ✚ Leverage already existing competences (e.g. sales force, connections in the healthcare industry, drug suppliers etc.)
- ✚ Less capital intensive
- ➖ Less control of NME(s) and assigned revenues

Acquisition

Acquire established pharma player(s) in the Saudi market:

- ✚ Leverage from already existing competence
- ✚ More diverse offering for end clients
- ✚ Core parts of business model are controlled in-house
- ➖ Significant up-front investment required

Licensing

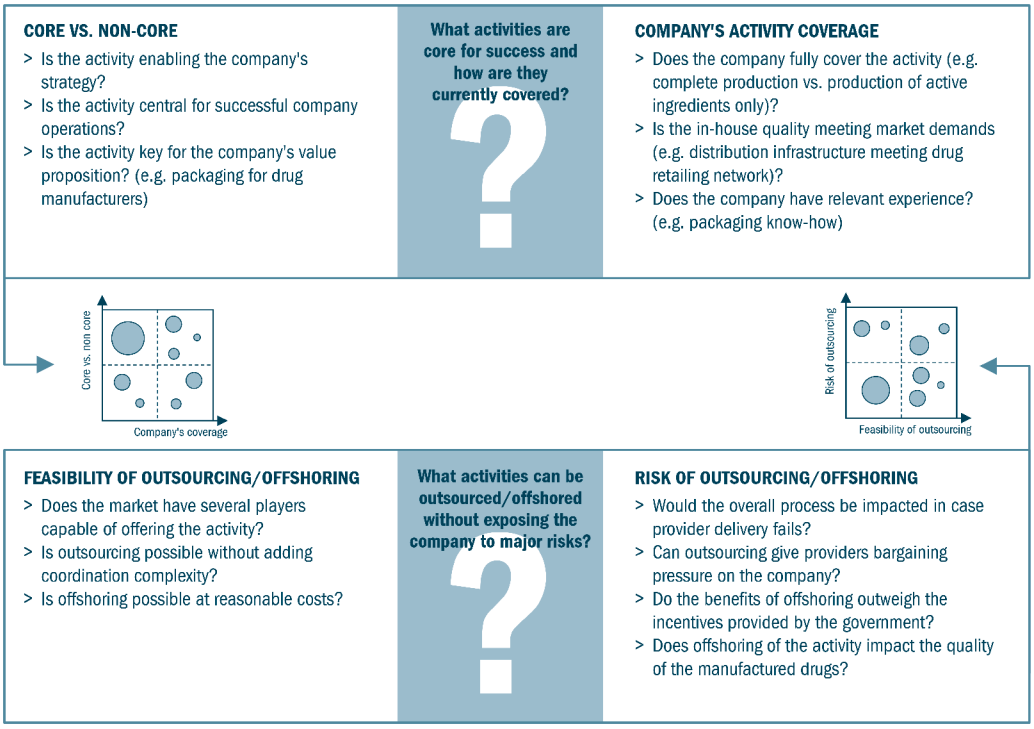
License the right to necessary intellectual property:

- ✚ Limited resources needed to perform the activity
- ✚ Fast and flexible
- ✚ Inhouse control of the activity
- ➖ Dependent on licensing agreements

Recalibrating scope/scale of activity coverage

In order for domestic players to be able to successfully compete in the generics market segment, it is essential for them to conduct a detailed activity assessment with the ultimate goal of reducing the scope or outsourcing/offshoring selected activities to LCCs.

FIGURE 11: ACTIVITY ASSESSMENT FRAMEWORK



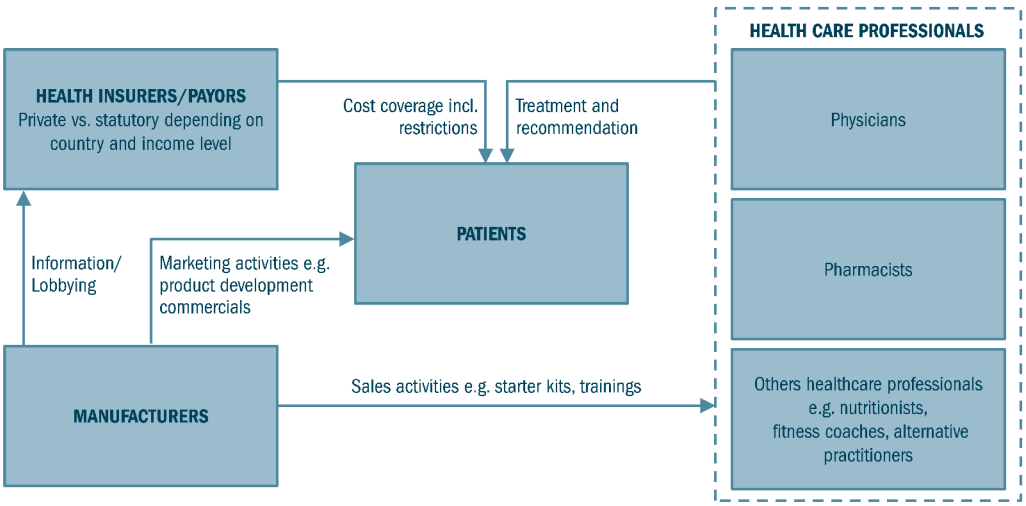
Outsourcing/offshoring non-core activities to LCCs could potentially allow local pharma players to focus on offering state-of-the-art services further down the value chain as well as adjusting the scale and scope of business in line with changing market conditions and customer requirements.

Building brand equity

Pharma players are increasingly focusing on building their brand equity driven by the rise of price-focused generic players and the intensifying struggle to identify new blockbuster drugs. Hence, established players are investing in strengthening their brand equity as one of the key levers of sustaining their firm's long term success. However, the nature of the pharma industry poses unique complexities in terms of brand management and consumer targeting due to:

> **Strong dependence on patents:** Given the industry's patent-based nature, manufacturers need to manage the dilemma of investing in product branding vs. corporate branding – The benefits of investing in patent-expiring drugs should be carefully weighed against the risks of the penetration of low cost generics
> **Regulated environment:** Regulations increasingly fragment the market with recent drug approvals encompassing more specialized therapies targeted at smaller sub-groups of patients – The branding and marketing of niche products strains most feasibility studies and should hence be assessed on a case-by-case basis
> **Diverse target groups:** Beyond addressing patients, prescription products in particular involve a diverse set of stakeholders including healthcare professionals, manufacturers and insurers. The aforementioned stakeholders influence and even make decisions on behalf of patients – A comprehensive branding strategy should target the entire landscape of stakeholders to achieve an optimal outcome

FIGURE 12: POTENTIAL TARGETS OF A COMPREHENSIVE BRANDING STRATEGY



Survival of the fittest

For domestic players, the rosy period might be drawing to a close. As the Saudi Arabian pharmaceuticals market expands in line with the increasing healthcare needs of a growing population, foreign manufacturers lured by the promise of greener pastures will seek to expand their domestic footprint. In parallel, the need to control spiraling healthcare costs will drive the trend towards more frugal pharmaceutical procurement in both the public and private sectors. The net result of these trends will be a sea-change in the Saudi Arabian pharmaceuticals landscape, with domestic manufacturers struggling to compete with the brand strength of traditional Big Pharma or the low cost-base of LCC manufacturers.

In order to survive, domestic players – manufacturers in particular – must assess their strategic positioning in the market and consider how best to capitalize on new opportunities in a changing environment. Possible strategies include a reassessment of the value creation architecture and adopted business model as well as the building-up of a strong brand equity.

Ultimately, the best-positioned players will be those who understand their respective strengths and weaknesses and possess the strategic agility to navigate the changing landscape accordingly – only the fittest will survive.

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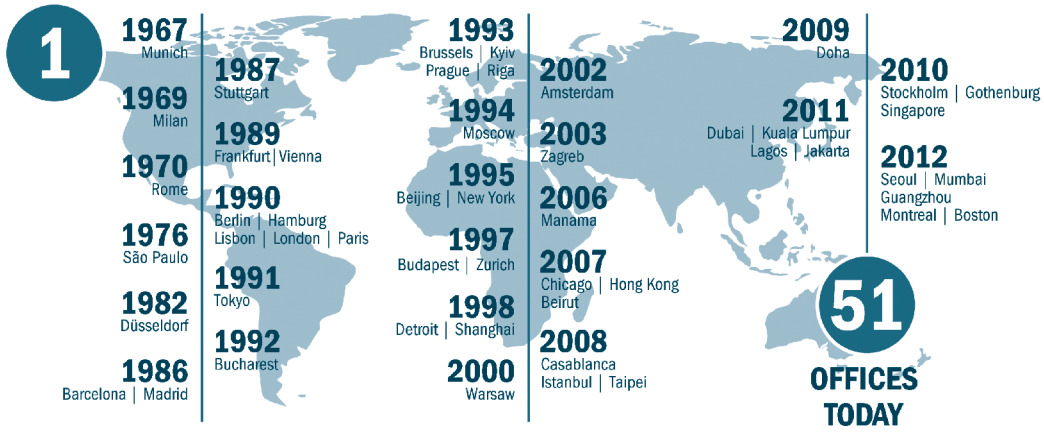
Roland Berger's business is organized into global functional and industry competence centres. Its practice areas include corporate development, marketing and sales, operations strategy, restructuring and corporate finance and information management. Industry specialties include automotive, consumer goods and retail, energy and chemicals, engineered products and high-tech, financial services, information communications, pharmaceuticals and health care, public services and transportation.



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