January 29, 2011
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In-Focus Report

Saudi Pharmaceuticals Sector Review

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Executive Summary

- Saudi pharmaceutical market size is estimated to have reached-SAR10.29 billion (USD2.74 billion) in 2008,
- Market size is expected to post a compound annual growth rate (CAGR) of 5.74% and is estimated to reach SAR13.1 billion (US$3.49billion) by 2012,
- Local manufacturers had supplied around 16% of the total pharmaceuticals market, while remaining 84% were imported from other countries,
- Leading domestic players/manufactures are; SPIMACO, Tabuk Pharmaceuticals Company, Jamjoom Pharmacies, Al-Jazira Pharmacies, Riyadh Pharmacies, and Saja Pharmacies, and foreign firms including; GlaxoSmithKline (UK), Pfizer, Novartis, Astra, MSD and Janssen, etc,
- Combined value of local manufacturing is estimated to have reached SAR1.62 billion in 2008 and expected to reach SAR2.12 billion in 2012,
- The imports of pharmaceuticals are estimated to grow by 5.25% and projected to reach SAR10.81billion in 2012 from SAR8.67 billion in 2008,
- About 54% of pharmaceuticals by value were purchased by the public sector, while remaining 46% bought by private healthcare facilities and out-of-pocket purchases by individuals,
- Over 5,700 registered drugs are sold through more than 4,500 pharmacies, and Over-the-Counter (OTC) sale stood at SAR692 million in 2008,
- There are no looming threats to the business of pharmaceuticals sector. However, lack of indigenous R&D in Pharmaceuticals is one of the major limitation to develop new drugs locally.

Introduction

The Saudi pharmaceutical market is the largest in the GCC. The growing population and its increasingly westernized lifestyle have driven up the level of chronic diseases in the Kingdom. This, alongside the increased wealth of the nation, encourages not only the demand for pharmaceuticals but the demand for patented products. However, the rather strict regulatory regime and price control of the government favor local pharmaceutical manufacturers, thereby intensifying competition.

The vast majority of the market is currently provided by imports, mainly comprised of patented and over-the-counter (OTC) drugs. Local production is mainly involved in the secondary manufacturing of generic products. In 2008, patented drugs dominated the market, with generic drugs trailing well behind. However, the market share of patented drugs is expected to erode over the 2009 – 2012 forecast period as mandatory price cuts are imposed, generic-friendly policies enacted and registration for innovative drugs delayed in laboratory analysis.

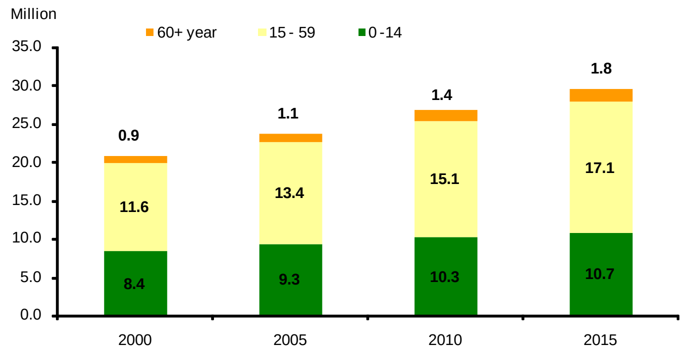
The leading Saudi pharmaceutical companies are Saudi Pharmaceutical Industries and Medical Appliances Corporation (SPIMACO), Tabuk Pharmaceuticals Company and Jamjoum Pharmacy with market shares of 7.2%, 3.9% and 3.2%, respectively in 2009. Multinationals tend to enter the market through joint ventures with Saudi firms. Currently there are 9 joint venture in the Kingdom, and GlaxoSmithKline's (GSK) strong product portfolio allows it to dominate the market with a share of 10.3% in 2009. Despite the registration struggles facing foreign firms, an increase in their presence is forecasted.

Market Determinants

The most significant factor driving pharmaceutical demand is the rapidly growing population. Total population has grown at a CAGR of 2.4% over the 2000 – 2008 period and is expected to continue accelerating at this rate, reaching 28.5 million by 2012. Although the population is demographically young, the percentage of Saudis aged 60 or over is gradually rising. This, alongside a growing number of civilization diseases, is increasing the need for pharmaceuticals in the Kingdom. A growing level of lifestyle related diseases has been observed within the population, with the total number of inpatient and outpatient visits at roughly 4 times the population size in 2008. Examples of such diseases include diabetes, gastrointestinal disorder, cardiovascular diseases and respiratory illnesses such as ophthalmologic.

Pharmaceutical growth is also driven by increased longevity. Life expectancy in Saudi Arabia has significantly improved due to higher standard healthcare facilities,

Chart 1: Saudi Population Demographics

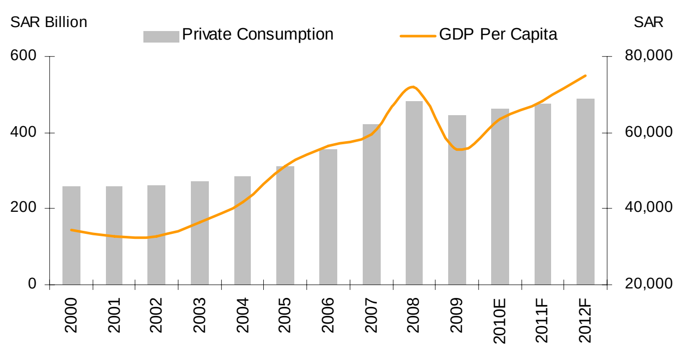


Source: Central Department of Statistics (CDS) and NCB Estimates

access to modern water and sanitary infrastructures, and better educational standards. Over the past two decades, life expectancy has increased from 68.1 years in 1989 to an estimated 75.3 years in 2009. Furthermore, the death rate per 1000 inhabitants has decreased from 2.62 in 2005 to an estimated 2.47 in 2009, marking a decline of more than 6%.

The rising wealth and private consumption of the population account for a great deal of pharmaceutical market expansion. Despite dipping slightly in 2008 in light of the global economic crisis, GDP per capita has been steadily rising for the past decade at a CAGR of 6.27% and is estimated at SAR60,669 for 2010. Although there is a major unemployment problem within the Kingdom, government benefits, subsidies and high levels of personal wealth will keep the consumer market active. We see confidence returning in 2010, with a private consumption growth rate of 3.0%, compared with an estimated contraction of 3.0% in 2009. Both consumption and GDP per capita are expected to continue rising over the forecast period, climbing 6% and 18%, respectively by 2012.

Chart 2: GDP Per Capita and Private Consumption

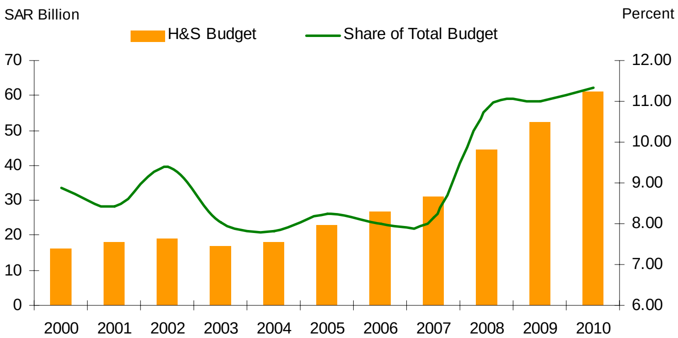


Source: SAMA, CDS and NCB Estimates

Business Environment and Regulatory Regime

The primary objective of the Saudi social development strategy is to provide a high standard of health facilities to the general public. For 2010, the government has allocated SAR61.2 billion towards health and social affairs, a 17% increase on the previous year's budget. Saudi nationals and residents currently have access to over 400 hospitals, 2,075 healthcare centers and 850 private clinics. The continued government appropriations to the healthcare sector over the years have undoubtedly stimulated the pharmaceutical business environment.

Chart 3: Health and Social Development Budget



Source: CDS

The main regulatory authority in the country is the Ministry of Health (MOH), which requires all pharmaceutical companies to be registered. The registration process takes roughly 6 to 18 months and licenses must be renewed every 5 years. The entry of new pharmaceuticals into the market must be approved by the MOH in a two-fold process: initial approval by a primary committee and a product analysis done by local laboratories, even for drugs with U.S. or EU Food and Drug Administration approval. Foreign companies argue the laboratory analysis is unnecessary and delays the introduction of new medication by taking up approximately 50% of total approval time. Drug makers believe that the system would be accelerated if the two processes occurred simultaneously.

However, it is important to note that the extent of analysis done on products in the Kingdom is no more than what Saudi pharmaceuticals drugs are subjected to in foreign jurisdictions. Thus, it can also be argued that the MOH is taking the necessary steps to ensure the health and safety of its public.

The Saudi Food and Drug Authority (SFDA), established in 2003, is responsible for developing and enforcing a transparent regulatory system for the pharmaceutical sector. To create a single interface between private suppliers and the public sector, the government has set up a National Company for Unified Purchase of Medicines & Medical Appliances with a capital of SAR2 billion in 2007. The SFDA is also currently in negotiations with a number of international pharmaceutical companies to create a new draft regulatory system for drug approvals.

WTO Accession

Under the Saudi WTO agreements, the commercial presence of foreign hospitals and pharmaceutical companies is permitted via joint ventures with Saudi firms. Furthermore, the Kingdom revised its legislation, particularly in the areas of Intellectual Property (IP) protection, import licensing, customs tariffs and fees. Saudi Arabia has agreed to implement Trade-Related Aspects of Intellectual Property (TRIPS) without any transition period, and has instilled the following regulations over the past 7 years: Trademarks Laws, Copyright Laws, Laws on Patents, Border Measures Regulations and Rules of Protection of Trade secrets (including the protection for undisclosed pharmaceutical data). The last law ensures that test data submitted to obtain marketing approval will be protected against unfair commercial use.

Although the improved IP laws limit local firm's ability to make generic version of patented drugs, foreign investors argued that the new patent laws introduced in 2004 did not provide adequate IP protection for all drugs. Under the new regime, many pharmaceutical products were denied patents because it was determined that they were not "novel", as they had been publicly patented in other jurisdictions a year before their cases were considered in Saudi Arabia. In September 2009, the King approved a mechanism to protect Exclusive Marketing Rights (EMR) for certain pharmaceutical products which lost patent protection during the 2004 transition. EMR protection in Saudi Arabia expires on the same date the patent expires in the United States of the European Union.

Other drug makers claim that the pricing criterion of registration acts as a "non-tariff" barrier. Prices of pharmaceuticals must be approved by the MOH. The drug registration departments use a price reference system that considers the price of the drug in its country of origin, as well as other 30 other markets where prices are lower, and fixes the lowest possible price for the product. Drug makers argue that these markets are not comparable to Saudi Arabia in terms of living standards, drug consumption patterns, income levels or regulatory environments. Furthermore, in February 2009, the SFDA began fixing CIF (Cost, Insurance and Freight) prices and retail prices in Saudi riyals. This means that importers are likely to lose or gain depending on the fluctuations of the exchange rates.

GCC Common Drug Policy

The GCC pharmaceutical procurement system is based on a unified drug policy to procure pharmaceuticals being consumed in the 6 member countries. The common drug policy ensures joint purchases of pharmaceuticals through Gulf tenders floated by the Secretariat General of Health, Riyadh, and other respective health ministries.

These bulk purchases enable the member countries to acquire quality medication at suitable prices, as well as adopt an efficient Drug Quality Surveillance Reporting System to closely monitor the efficacy and safety of the drugs. Under the common drug policy, all centrally registered pharmaceuticals are automatically registered in individual GCC countries and are exempted from undergoing the lengthy registration procedures. This effectively gives regional producers preferential treatment for entry into the GCC markets, particularly in the tendering system for public pharmaceutical drug purchases.

Pharmaceutical Market Size

The market size of the Kingdom's pharmaceutical sector is calculated by analyzing data from the publications of domestic firms, Saudi import statistics and annual MOH reports. In 2008, the Saudi pharmaceutical market accounted for roughly 65% of all drug sales in the GCC region. Aggregate demand for pharmaceuticals in the Kingdom is estimated to have grown by 21% to SAR 11.17 billion in 2008. Roughly 54.6% of sales were derived from the public sector - which includes the MOH, Ministry of Defense (MOD), and Civil Security -, while the remaining 45.4% were derived from private healthcare facilities and out-of-pocket purchases by individuals. Furthermore, per capita market demand of pharmaceuticals in Saudi Arabia reached an all time high of SAR450 in 2008, well above the GCC average of SAR263.

Over the forecast period 2009-2012, the Saudi pharmaceutical market is set to experience steady growth at a CAGR of 5.92%. Population growth, ageing and affluence will be the main drivers of this expansion, with GDP per capita forecast to reach SAR75,034 by 2012. Furthermore, healthcare provision, modernization and expansion, as well as the establishment of more private facilities are also aiding the sector's growth. Market value is forecast to rise from SAR11.81 billion in 2009 to roughly SAR14.04 billion in 2012. The public sector will continue to account for the majority of market purchases, its share rising by roughly 1% per year to reach 58.2% in 2012. Meanwhile, pharmaceutical demand per capita will increase from SAR465 in 2009 to SAR515 in 2012.

However, the price control and regulatory regime of the Kingdom may have a negative impact on the market developments in the medium term. Although drug expenditure increased significantly in 2008, it only rose marginally as a component of GDP, and represented a relatively minor 0.63% of the total. This is due to the fact that GDP is driven by the growth of the oil sector, which is rising at a higher rate than that of population growth—the main driver of pharmaceutical expenditure. We expect that the country's wealth and demand for the latest in medical advancements would have allowed the pharmaceutical sector's share of GDP to have risen and peaked in 2009.

The Saudi government has introduced the automatic price revision system of all pharmaceuticals every five years. Furthermore, once the validity time of a patent passes, the prices of the product's generic version are gradually reduced by 20%. These regulatory developments will constrain the earnings of pharmaceutical companies. Consequently, pharmaceutical expenditure as a percentage of GDP is forecast to fall from 0.84% in 2009 to 0.69% in 2012. However, the MOH maintains that this pricing mechanism is necessary to provide the best health services to both citizens and residents.

Foreign Trade

The Saudi pharmaceutical sector is heavily reliant on imports, accounting for approximately 84% of the market share in 2008. This is because the Kingdom's considerable wealth means that patented drugs remain the favored treatment option. Imports of pharmaceuticals stood at SAR 9.65 billion in 2008 and are estimated to grow at a CAGR of 4.64% over 2009 – 2012 to reach SAR11.57 billion by 2012. European manufacturers supply the majority of imports, followed by the U.S., the Middle East and North Africa. In the GCC, the UAE has been the dominating exporter to Saudi Arabia, accounting for SAR348 million worth of pharmaceuticals sales.

The remaining 16% of market supply is provided by domestic pharmaceutical companies who target generic products. Saudi pharmaceutical manufacturers are mainly involved in secondary manufacturing, through the use of active ingredients (substances in a pharmaceuti-

Table 1: Saudi Pharmaceutical Sector

Year	2008	2009	2010	2011	2012
Market Value (SAR bn)	11.17	11.81	12.50	13.24	14.04
Imports (SAR bn)	9.65	10.10	10.57	11.06	11.57
Local Production (SAR bn)	1.52	1.72	1.94	2.19	2.47
Share of Public Sector Purchases	54.6%	55.8%	56.3%	57.2%	58.2%
Share of Private Sector Purchases	45.4%	44.2%	43.7%	42.8%	41.8%
Expenditure Per Capita (SAR)	450	466	481	498	515

Source: CDS, Company Annual Reports and NCB Estimates cal drug or a pesticide that are biologically active) due to the increasing number of primary products losing patent protection worldwide. At present, there are about 27 manufacturing facilities in the Kingdom that produce the following products: Augumentin, Viagra, Snafi, Lipto, Rofenac, Klavox, Zithromax, Nexium, Dermove, etc. The combined value of local production is estimated at SAR 1.62 billion in 2008 and is forecast to grow at a CAGR of 12.88% over the forecast period, reaching SAR2.47 billion by 2012.

The Kingdom's exports and re-exports of pharmaceuticals to regional countries reached SAR625 thousand in 2008. This value is expected to rise considerably at a CAGR of 20% over the forecast period, reaching nearly SAR1.30 million by 2012. This is attributed to government efforts to promote local pharmaceutical manufacturing, which have resulted in domestic production gaining market share. Such efforts include government subsidies in the form of interest-free capital and reduced utility costs. However, exports will continue to represent a minor component of the market as local Indusial activity remains concentrated in basic drugs.

Chart 4: Pharmaceutical Supply

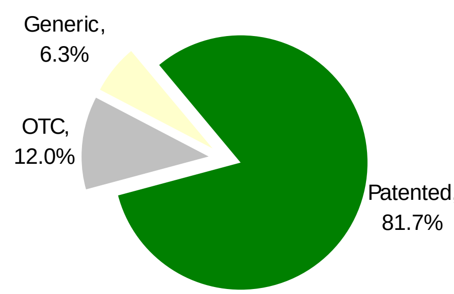
Source: CDS, Annual Reports and NCB Estimates

Pharmaceutical Subsectors

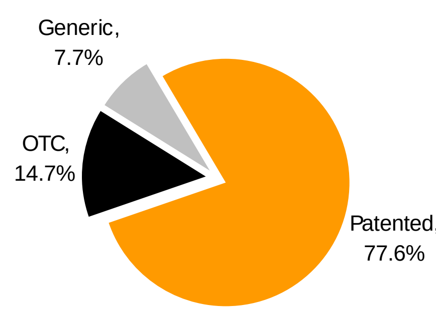
By examining imports and local production, we can further breakdown the pharmaceutical market into subsectors: patented drugs, generic drugs and over-the-counter (OTC) drugs. In 2008, patented drugs dominated the market, with the share of generic and OTC drugs representing only 6.3% and 12.0%, respectively. However, the market share of imports, and therefore the subsector patented drugs, is expected to erode over the forecast period as mandatory price cuts are imposed, generic-friendly policies enacted and registration for novel drugs is delayed in laboratory analysis.

By 2012, the ratio of imports to local products is forecast to reach 82:18. The market share of patented drugs is expected to fall to 77.6% as generic drugs capture 7.7% of the market. The relatively low prices of generics in relation to original brands will be the main driver of this growth. Presently, data exclusivity is not provided to innovative products that have not been directly patented in the country. The OTC subsector is also forecast to gain momentum, with its market share rising to 14.7% on the back of growing consumer income and stronger advertising support. Nonetheless, the TRIPS-compliant regulation, pressure from international research-based pharmaceutical companies and continued demographic changes may play a role in stimulating the growth of patented drugs and improving their position in the Saudi market in the long run.

Chart 5: Pharmaceutical Subsectors



2008, SAR11.17 billion



2012, SAR14.04 billion

Source: Industry Data, Company Reports, BMI and NCB Estimates

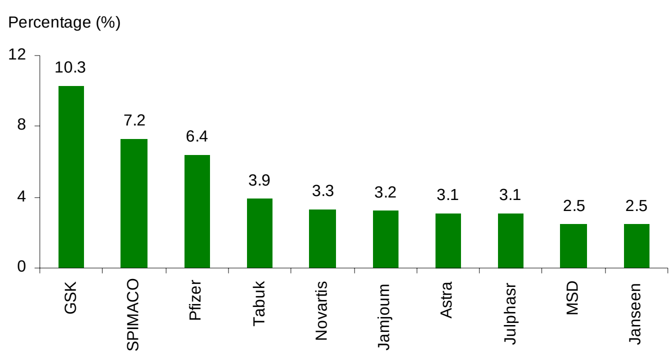
Leading Manufacturers

The three leading domestic players in the pharmaceutical industry are Saudi Pharmaceutical Industries and Medical Appliances Corporation (SPIMACO), Tabuk Pharmaceuticals Company, and Jamjoom Pharmacy. SPIMACO is the Saudi Arabia's major pharmaceutical manufacturer and the second-ranked drug company in the Kingdom, following GlaxoSmithKline (GSK). Its main facility is located in Qassim Industrial City, where it produces over 150 products, including brand-name drugs for multinational companies as well as its own generic forms of prescription and OTC medication. The company has its own distribution network, run by its subsidiary

ARAC Healthcare Company, and its leading products include antibiotics, analgesics, vitamins, anti-rheumatics and cough/cold remedies. SPIMACO controlled roughly 7.24% of total market sales in 2009 and has recently announced the establishment of a SAR800 million Active Pharmaceutical Ingredient (API) facility.

Tabuk Pharmaceutical Manufacturing Company is the second largest domestic manufacturer with a 6.4% market share in 2009. The company formulates, registers, produces and markets generic, prescription and, recently, OTC drugs. TABUK offers 86 branded generic drugs to 16 countries in the Middle East, North Africa, U.S. and Europe, and its products were the first to be authorized for sale in European countries such as France and Denmark. It also produces eight innovative products under licensing for the Saudi market, in agreements with Japanese, Korean and European drug makers. Jamjoom Pharmacy is the third largest local manufacturer of pharmaceuticals and accounts for roughly 3.2% of market share. The company produces and distributes 70 pharmaceutical products, including brand names Aciloc, Amvasc, Azi-Once, Ciproxen, Duracan, etc. The company also exports products to fifteen other countries in the Middle East and Africa region.

Chart 6: Leading Pharmaceutical Manufacturers, 2009



Source: Company Annual Reports, Industry Data and NCB Estimates

Multinational presence in the Saudi pharmaceutical sector is mostly in the form of joint ventures with Saudi firms. To encourage local manufacturing, the government provides incentives to both multinational subsidiaries and domestic companies, including free property leases, interest free loans and government subsidies. There are currently nine joint ventures in the market with a cumulative foreign investment of SAR195 million. The single largest investor is Al-Hayat Factory for Medical Products, a Jordanian company with roughly SAR60 million invested.

The largest UK investor in the market is GSK, which established production operation in 1992 and is currently the leading pharmaceutical company with 10.8% of market share. The company has a joint venture with local company Banaja Saudi Import, known as Glaxo Saudi Arabia, which has a 51% stake in the subsidiary. Despite its considerable presence in the Kingdom, GSK's lead has been facing increased competition from SPIMACO, as well as Novartis on the back of its recent acquisition of BMS's portfolio of OTC brands.

The SAJPHCO is another joint venture between Japan International Development Organization (JAIDO), Sankyo, Astellas, Marubeni and Saudi firm Tamer. The company manufactures products strong in the treatment of diabetes, cancer and gastro-intestinal diseases under the Sankyo and Astellas names. This portfolio of products appropriately fits the epidemiological profile of the GCC. Another nation attempting to penetrate the Saudi pharmaceutical market is India. Indian drug maker Ranbazy began this initiative, as the first of it's country to register in the Kingdom. Meanwhile, the Kingdom's drug registration system requires that drugs have been previously marketed in two 'developed' markets before it can be approved in Saudi Arabia. Although the struggle of entering the market remains apparent, an increase in joint ventures is expected in the short-term.

Conclusion

The Saudi pharmaceutical sector is propped up by the sizeable population and their wealth, as well as a steady annual growth of the health and social development spending. Over the 2009 – 2012 forecast period, the market is expected to post a CAGR of 5.92%. At wholesale prices, total value of market demand is expected to increase from SAR11.17 billion in 2008 to SAR14.04 billion by 2012. Expenditure in the sector is largely derived from the public sector, whose share of demand is forecast to rise by approximately 1% per year reaching a total market share of 58.2% in 2012.

The price controls and IP regime favor domestic and regional production, which may stint foreign investment in the sector. Furthermore, the Saudi government has introduced automatic reductions in the prices of medicines every 5 years. Although pharmaceutical expenditure will rise in absolute terms as pointed above, these factors will reduce its share as a percentage of GDP from 0.84% in 2009 to 0.69% in 2012.

To meet the increasing demand for pharmaceuticals in the Kingdom, imports are expected to grow at a CAGR of 4.60%, settling at SAR11.57 billion in 2012. However, increased government efforts to promote local pharmaceutical manufacturing will bring about faster growth in local production. The value of local production is estimated at SAR 1.62 billion in 2008 and is forecast to grow at a CAGR of 12.88% over the forecast period, reaching SAR2.47 billion by 2012. Although boosted domestic manufacturing will lead to a surge in exports, indusial activity remains concentrated in generic drugs, the smallest component of the market. The Patented drug subsector is expected to continue dominating market, however, its share is forecast to fall as bias regulatory policies and price cuts encourage growth in the remaining subsectors. By 2012, patented drugs will capture only 77.64% of the market, while the share of OTC and generic drugs will rise to 14.67% and 7.69% respectively.

SPIMACO, Tabuk Pharmaceutical Manufacturing Company and Jamjoum Pharmacies are the leading Saudi pharmaceutical companies in 2010, with estimated market shares of 7.25%, 3.9% and 3.2%, respectively. However, increased multinational presence through joint ventures is forecasted as TRIPS-compliant regulation, pressure from international research-based pharmaceutical companies and continued demographic changes stimulate the demand growth of patented drugs.

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