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INDIA PHARMA SUMMIT 2012

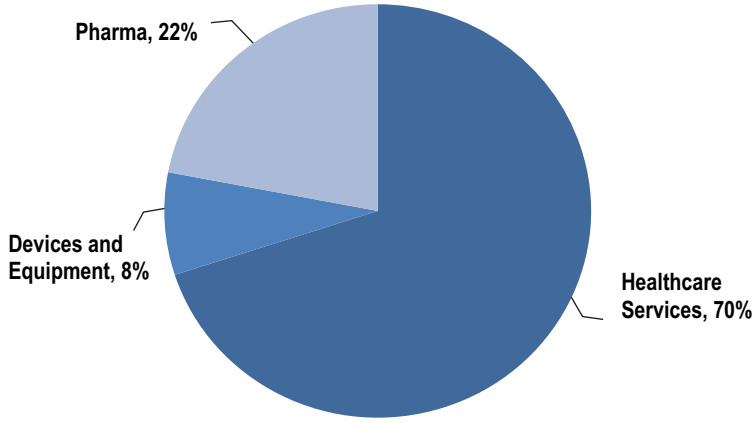
IPS

Section A: Access to Medicines

The Indian Healthcare Market

The Indian healthcare industry's value was pegged at USD 68.4 billion in 2011, and is expected to reach USD 137.5 billion by 2016. Driven by domestic as well as global markets, the Indian pharmaceutical market is poised to grow at compounded annual growth rate of 15% percent over the next 5 years.

Chart 1 shows the segmental breakup of the Indian healthcare market as of 2011.



Note: All figures are rounded; the base year is 2011.
Source: Frost & Sullivan

Access to Medicine - Challenges

Expenditure on Healthcare

India is one of the largest exporters of generics and life-saving drugs. The Indian pharma market is currently ranked 3rd-largest globally in terms of volume and is poised to be 10th-largest in value by 2015.

As compared to BRIC peers (BRIC comprises Brazil, Russia, India, and China), India has the least spending on healthcare as a percentage of GDP and has the highest out-of-pocket expenditure on private healthcare as a proportion of total health expenditure.

Table 1 shows BRIC nations' healthcare expenditure, compared with two developed nations - The USA and France.

Table 1: Nation-wise comparative healthcare expenditure (2009)

Indicator	India	Brazil	China	Russia	USA	France
Total expenditure on health as a percentage of gross domestic product	**4.2**	8.8	5.1	5.6	17.6	11.9
General government expenditure on health as a percentage of total expenditure on health	**30.3**	43.6	52.2	63.4	47.7	77.8
Per capita total expenditure on health at average exchange rate (US$)	**44**	734	191	476	7960	4840
Out-of-pocket expenditure as a percentage of private expenditure on health	**86.4**	57.2	78.9	82.1	23.4	33.1

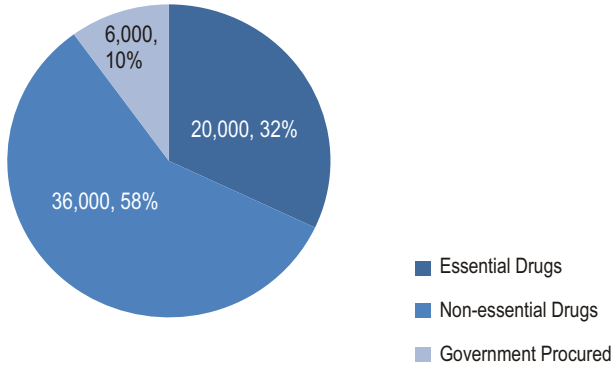
Source: WHO World Health Statistics Report 2012

The High Level Expert Group (HLEG) Committee on Universal Health Coverage in India observed that Government-procured drugs account for only 10 percent of total value of drugs sold in the Indian pharma market. This indicates that the private sector plays a major role in medicine distribution with government's role as a regulatory authority.

Chart 2 depicts the committee's estimates of Government's share of drugs purchased vis-à-vis Essential and Non-essential Drugs in open market.

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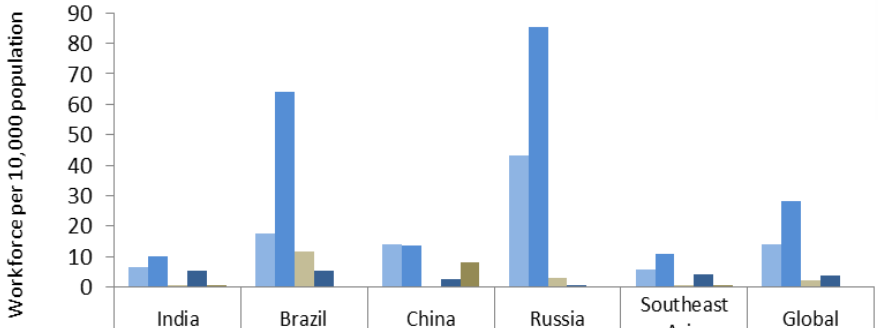
Government's share of drugs purchased vis-à-vis Essential and Non-essential Drugs in open market (in INR Cr)



Source: HLEG Report on Universal Health Coverage for India

Chart 3 indicates health resources in India as compared to other nations in BRIC and Southeast Asia 2010

Chart 3: Health Resources: India vs BRIC vs SE Asia 2005-2010



	India	Brazil	China	Russia	Southeast Asia	Global
Physicians	6.5	17.6	14.2	43.1	5.6	14.2
Nurses and midwives	10.0	64.2	13.8	85.2	10.9	28.1
Dentistry personnel	0.8	11.7	0.4	3.2	0.7	2.2
Pharmaceutical personnel	5.2	5.4	2.5	0.8	4.1	4.0
Community health workers	0.5	0.0	8.3	0.0	0.8	0.0

Source: WHO World Health Statistics Report 2012

As evident in Chart 3, India lacks significantly in healthcare workforce as compared to other developing economies in BRIC as well as global averages.

Table 2: Hospital beds per 10,000 population, India vs SAARC 2005-2010

SAARC Nations	Hospital Beds
Nepal	50
Maldives	43
Bhutan	18
India	9
Pakistan	6
Afghanistan	4
Bangladesh	3

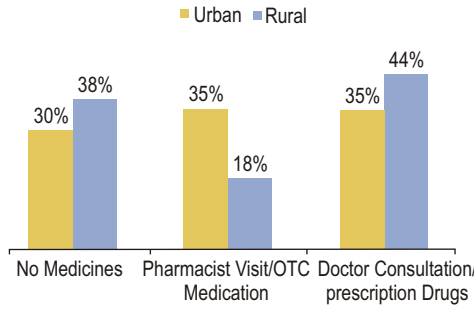
Source: WHO World Health Statistics Report 2012

Healthcare infrastructure in India is also found to be wanting as compared to many of its peers in SAARC nations.

Rural-Urban Divide

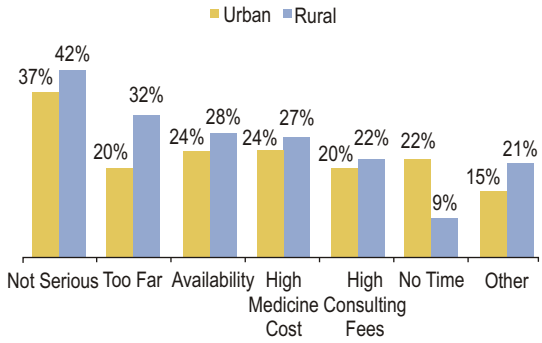
With the existing contrast with respect to development, infrastructure, and education; rural and urban India both present with their own set of barriers toward affordable and accessible healthcare.

Chart 4: Medication Pattern for Ailments in Last 6 Months



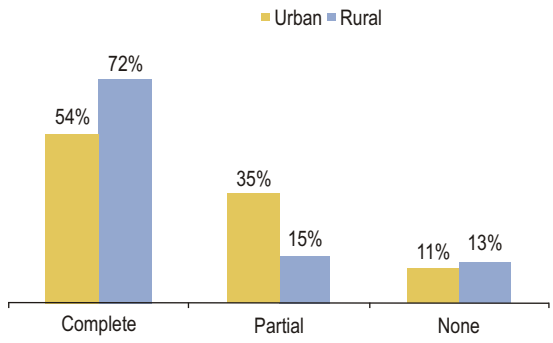
Source: Frost and Sullivan Analysis

Chart 5: Reasons for Non-medication during Ailment



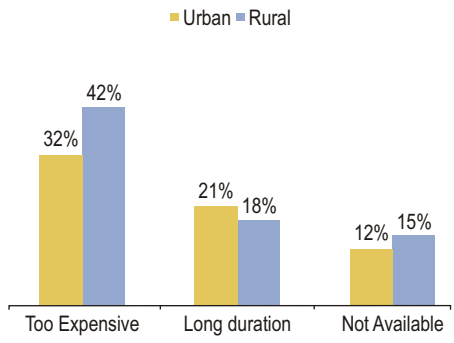
Source: Frost and Sullivan Analysis

Chart 6: Medicine Purchase during Last Ailment



Source: Frost and Sullivan Analysis

Chart 7: Reasons for Partial Compliance



Source: Frost and Sullivan Analysis

Note: Based on a survey of 500 urban and rural people suffering from any ailment in last 6 months, 2012 Frost & Sullivan

Rural Challenges

Lack of Integrated Health Infrastructure

Healthcare accessibility and infrastructure remain the biggest concerns in rural India, as major chunk of infrastructure and human resources are aggregated in urban and semi-urban areas. Considering that 68.8 percent of the Indian population resides in rural areas, this is indeed a major challenge. There are significant opportunities at present toward developing adequate health infrastructure in rural India. Infrastructure insufficiency is reflected in poor availability of not only access to medical treatment but also different healthcare services such as diagnosis of ailments as well as storage and dispensing of medicines.

Diagnostic Services

According to Frost & Sullivan, about 50 percent diagnostic devices are imported. These high-technology diagnostics are limited to major healthcare facilities mainly in urban areas. This is proving to be a major barrier toward increasing diagnostic facilities in rural areas.

Storage and Dispensing

Due to shortage of physicians and specialists in rural areas, local pharmacists play an important role in increasing awareness and providing diagnosis of ailments in addition to dispensing medicines. Though India has high number of pharmacy personnel, shortage of qualified pharmacists is a barrier in ensuring proper medicine access to the population.

With the increase in use of vaccines and temperature-sensitive biologic drugs, proper storage facilities for these medicines have become essential. The Parliamentary committee on Functioning of Central Drugs Standard Control Organization (CDSCO) has raised concern on storage of such temperature-sensitive drugs and vaccines even with availability of refrigeration facilities.

The National Rural Health Mission (NRHM) has been active in creating accessible health infrastructure and workforce in rural India. According to 5 year review of NRHM report, the budget allocation for the mission has increased from 6,730 Cr in 2005-06, to 14,050 Cr in 2009-10, with expenditure of more than 80% during first two and more than 90% in the next two years. Despite the addition of 122 Sub-centres, 651 Primary Health Centres (PHCs) and 1,463 Community Health Centres (CHCs), the shortfall of health workers and physicians at the created infrastructure remains a concern.

Health Insurance

Healthcare insurance could be a major support for the people, with out-of-pocket expenditure accounting for 86 percent of private expenditure on health; and private expenditure on health accounting for 71 percent of the total expenditure in India. According to Insurance Regulatory and Development Authority India (IRDA), non-life insurance penetration (ratio of premium to GDP) in India in 2010 stood at 4.4%.

According to the Planning Commission, in 2009-10 the total number of people Below Poverty Line (BPL) in rural areas stood at 27.82 Cr as compared to 7.64 Cr in urban areas. The rural BPL population is supported by Central and State Government insurance schemes.

Table 3 shows healthcare scheme/insurance coverage as of 2010

Table 3: Estimated Healthcare Scheme/Insurance Coverage (in M)

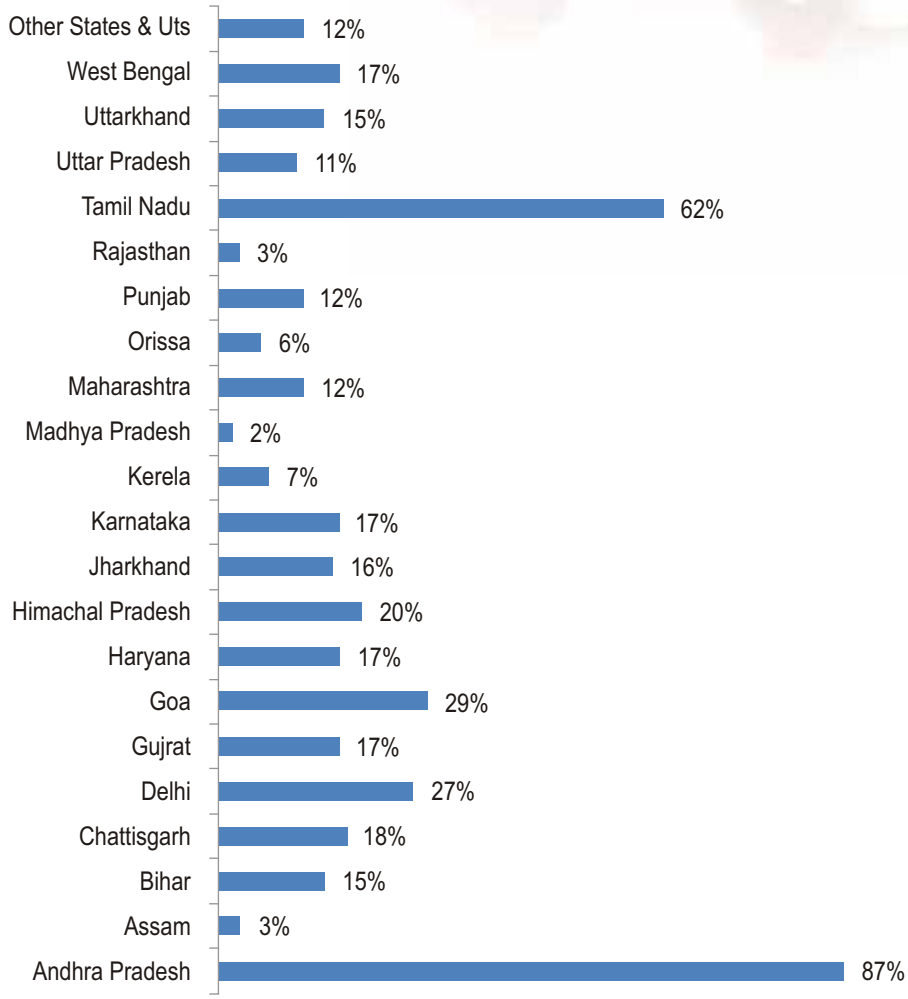
Scheme	Total covered population (in millions)
CGHS	3.0
ESIS	55.4
Rashtriya Swasthya Bima Yojana (RSBY)	79.5
Rajiv Aarogyasri Scheme (AP)	70.0
Kalainagar (TN)	35.0
Yeshasvini (KN)	3.0
Vajapayee Arogyasri Scheme (KN)	1.4
Total Government Sponsored Schemes	247.0
Private Health Insurance	55.0
Grand Total	302.0

Source: Public Health Foundation of India Report, 2011

Andhra Pradesh and Tamil Nadu are the leading states with respect to population covered by health insurance schemes in India, Chart 8 demonstrates the same.

** 'Chief Minister Kalaignar Insurance Scheme for life-saving Treatments' is now known as Chief Minister's Comprehensive Health Insurance Scheme*

Chart 8: Total Estimated Population Covered by Any Form of Healthcare Insurance in India (2010)



Source: Public Health Foundation of India Report, 2011

Some State Governments have enforced effective health insurance and reimbursement schemes such as 'Rajiv Aarogyasri Health Insurance Scheme' in Andhra Pradesh and Tamil Nadu's 'Chief Minister Kalaignar Insurance Scheme for life-saving Treatments*' in partnership with private service providers and insurance players, which has boosted health coverage in these states.

Rajiv Aarogyasri Health Insurance Scheme in Andhra Pradesh provides cashless health coverage of INR 1.5L to 2.5L per year to BPL families. With limited capacity of public hospitals to handle the large population to be covered, the scheme has involved private sector with the State acting as a payer. The scheme is implemented through private insurer Star Health Insurance. As of 2010, treatment worth over INR 2000 Cr was dispersed through it. The scheme is one of the most successful examples of Public-Private Partnerships in healthcare.

Lack of Awareness

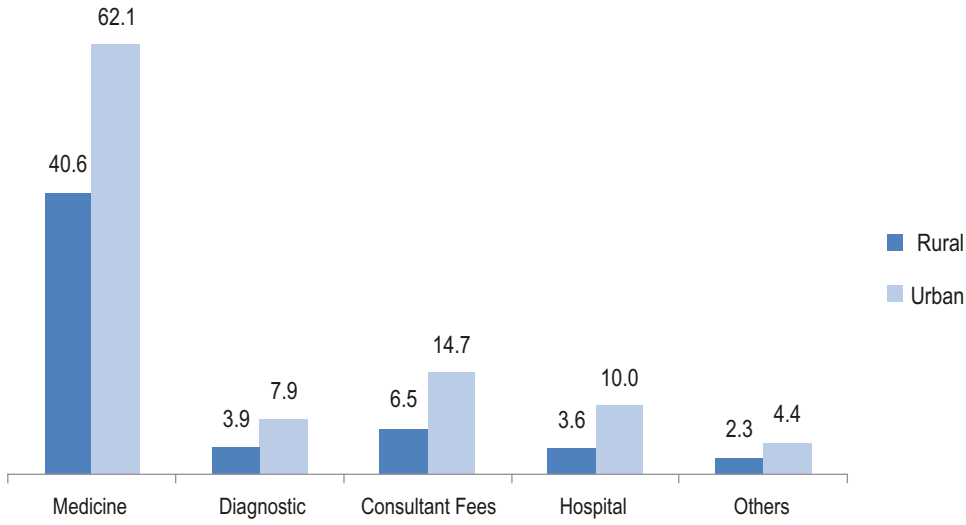
Focus on preventive healthcare and early diagnosis of ailments has been increasing globally in efforts to contain healthcare costs in managed care. Low levels of health literacy, presence of multiple systems of medicine, and low availability of diagnosis facilities are contributors to lack of awareness in rural India. Apart from infrastructure and affordability issues, awareness remains the key issue to be tackled in order to improve rural healthcare access.

Urban Challenges

Affordable Healthcare

Chart 9 shows the monthly per capita medical consumption cost in urban areas.

Chart 9: Monthly per Capita Medical Consumption Cost in Urban Areas



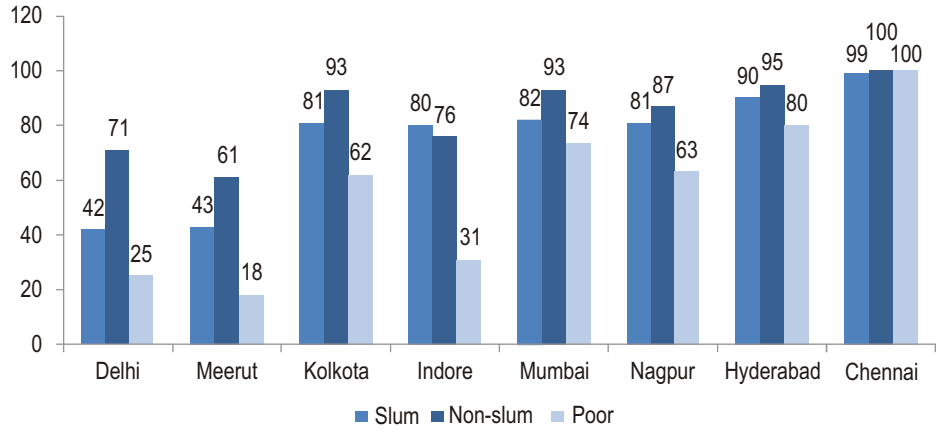
Source: NSS 66th Round Household Consumer Expenditure

According to the Planning Commission's report, approximately 74 percent of out-of-pocket expenses in urban areas are on account of medicine purchases. It has been observed that although average monthly spend on medicine, as compared to total spend on healthcare, is higher in rural areas; average monthly spend in urban areas is much higher in both institutional and non-institutional cases. Apart from high expenses on essential medicine, novel biologic life-saving medicines which are imported attract high customs duty and are therefore out of reach for most of the population.

Apart from cost of medicines, urban healthcare is more expensive with diagnostic, doctor/surgeon fees, and hospital charges all being twice as expensive as compared to rural areas.

Accessibility to Weaker Sections

Chart 10: Percentage of births during 2005-2006 in healthcare facilities/ with healthcare personnel/ with antenatal care



Source: Health and Living Conditions in Eight Indian Cities, NFHS 3

As seen in Chart 10, large portion of the economically weaker population in cities lack access to proper healthcare facilities/services. Penetration of healthcare services among the weaker sections in the cities is one of the major challenges toward increasing healthcare access. The National Urban Health Mission (NUHM) expected to start operations in 2013 is expected to address specific needs of the urban poor.

Medication Compliance and Self-Medication

Access to healthcare services is affected due to high consultation costs and rising cost of medicines. Unavailability of time due to hectic lifestyles in cities has also led to medication compliance issues in urban populace. With the high cost of medicine, a mistrust of prescribing doctors, and unavailability of medicine contributes to sub-optimal purchase and poor adherence to treatment regimen. With increasing reliance on sources of health information other than doctors, educated and professionals with high income place low faith in doctors. This is leading to increasing instances of self-medication, with over-the-counter (OTC) as well as prescription drugs.

Way Forward

With high involvement of the private sector in healthcare services in India, a collaborative approach between the Government and private players at different levels is necessary for increasing healthcare access. With high costs of healthcare, it is imperative that financial protection in the form of insurance is the way forward to ensure accessibility of healthcare services and medicine in a Public-Private Partnership (PPP) model.

Augmenting infrastructure in healthcare delivery and reducing out of pocket expenses is important and should be prioritized. Creating synergies between Government and private players to drive efficient healthcare systems across India is the need of the hour.

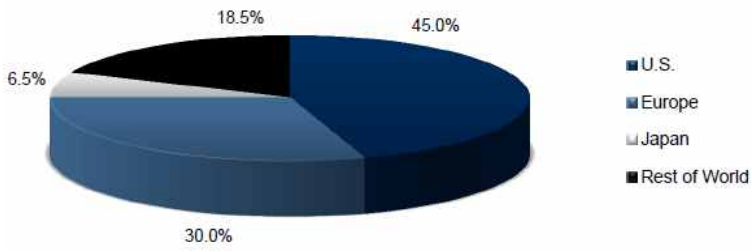
Section B: Global Outreach

Global Generics Pharmaceutical Market

The Global Generic Pharmaceuticals Market was estimated to be USD 123.85 billion in 2010, contributing a significant 14.5% of the USD 850 billion global pharmaceutical market. Blockbuster drugs worth USD 150.00 billion are due to lose patent protection between 2010 and 2017, unfolding immense opportunities for generic companies. The global generic pharmaceutical market is expected to reach USD 231.02 billion in 2017 growing at a 2010-17 CAGR of 9.3%.

Chart 1 shows the breakup of the global generic pharmaceutical market as of 2010

Chart 1: Generic Pharmaceutical Market, Breakdown by Country (Excluding India and China), 2010

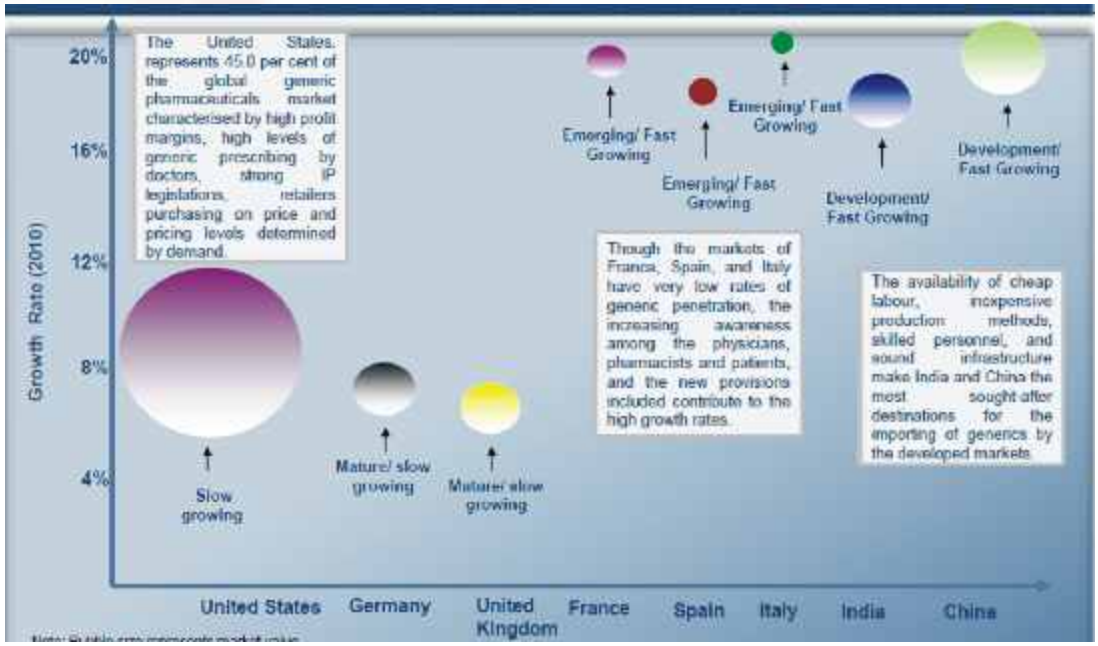


Note: All figures are rounded; the base year is 2010.
Source: Frost & Sullivan

As seen in Chart 1, United States is the world's largest generic pharmaceuticals market with a share of 45.0 %, valued at USD 55.78 billion and growing at a rate of 9.0 percent, while Europe ranks second, occupying 30 % market share of the global generics, valued at

USD 36.00 billion and growing at a rate of 8.0 percent.

Chart 2 shows the attractiveness of the major generic pharmaceutical markets



Note: Bubble size represents market value
Source: Frost & Sullivan

Key trends in Global Generic Pharmaceutical Market

Shift towards Emerging Markets

The balance in terms of healthcare expenditure and sales revenue will shift from developed markets to emerging markets as a huge potential still remains untapped in the emerging markets.

Consolidation within the Industry

Consolidation remains to be the key factor for the growth and sustenance of generic companies. Partnerships, mergers, acquisitions, and strategic alliances help both branded and generic companies to expand.

Increased Investment in R&D

Branded companies intend to venture into generics businesses to compensate for the sluggish growth in the branded sector. Similarly, large generics manufacturers seek to establish their own R&D entity by improvising their technical and development skills. This will give leading generic participants an edge in gaining market share over many smaller local generic participants.

Patent Benefits

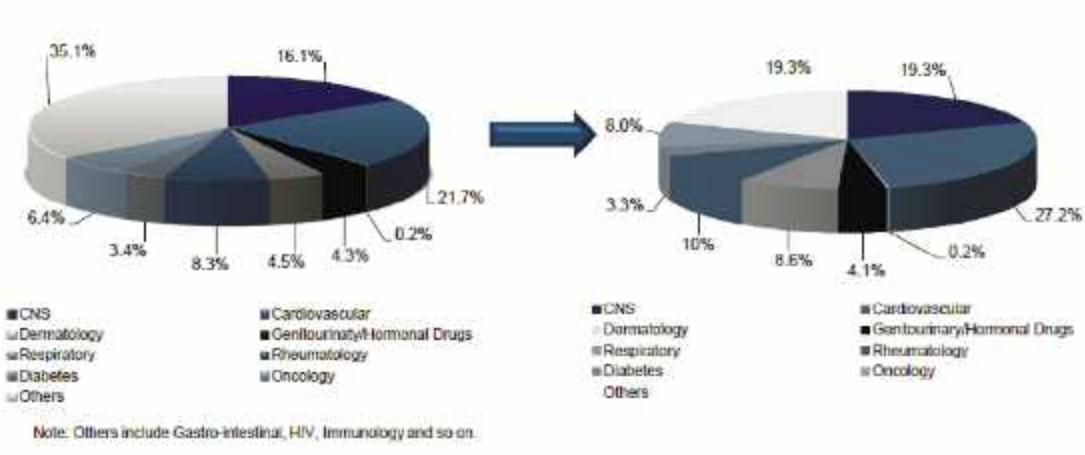
High revenue-churning blockbuster drugs are set to lose their patent protection in the forecast period and generic companies are proactive in filing applications for marketing rights.

New Product Launches

Trends in generics are shifting towards higher value biological therapies, biosimilars, and speciality segments where there is hardly any competition despite high profit margins.

Chart 3 indicates Global Generic Pharmaceutical Market for key therapeutic areas 2010-2017

Chart 3: Global Generic Pharmaceutical Market for key therapeutic areas 2010-2017



Note: All figures are rounded; the base year is 2010.
Source: Frost & Sullivan

As evident in Chart 3, the cardiovascular and CNS generic markets are expected to experience the fastest growth among all other therapeutic markets.

Key Industry Challenges

Threat from the Introduction of Authorised Generics by Innovator Companies

Innovator pharmaceutical companies have started producing generic versions of their own brands, which pose a major threat to independent generic companies in selling their own products. Innovator companies consider this as a means to compensate for the losses incurred in their market shares immediately after patent expiry and settle patent litigation between branded and generic companies to effectively manage the risk of Paragraph IV Patent challenges. Introduction of authorised generics potentially discourages the independent generic firms from challenging the drug patents, as the launch of authorised generics during the 180 days exclusivity period (under the Hatch-Waxman Act) not only reduces the incentives for patent challenges but also makes recovery of litigation expenses a complicated task. Though the FDA and the Federal Trade Commission currently favour authorised generics, it still remains a highly controversial issue.

Trends in generics are shifting towards higher value biological therapies, biosimilars, and speciality segments where there is hardly any competition despite high profit margins.

Judicious Efforts of Government to Control Rising Healthcare Expenditure will Drive the Generic Market

Funding for healthcare services by the government has seen an increasing trend year after year with an increase in the outbreak of diseases and changing population demographics.

In response to the rising healthcare expenditure, the government is looking for cost-effective alternatives such as generics which are priced almost 20 to 90 % less than the price of patented drugs. Therefore, several healthcare reforms favoring the manufacturers of generic drugs have been introduced in both developed as well as developing countries of the world, thereby saving more costs for investment in R&D.

Specific insurance coverage schemes introduced by the government and private participants for Medicare and Medicaid patients constitute nearly 41.0 % of the total healthcare expenditure. This will result in increased generic drugs consumption as the healthcare providers will look out for cost-effective alternatives.

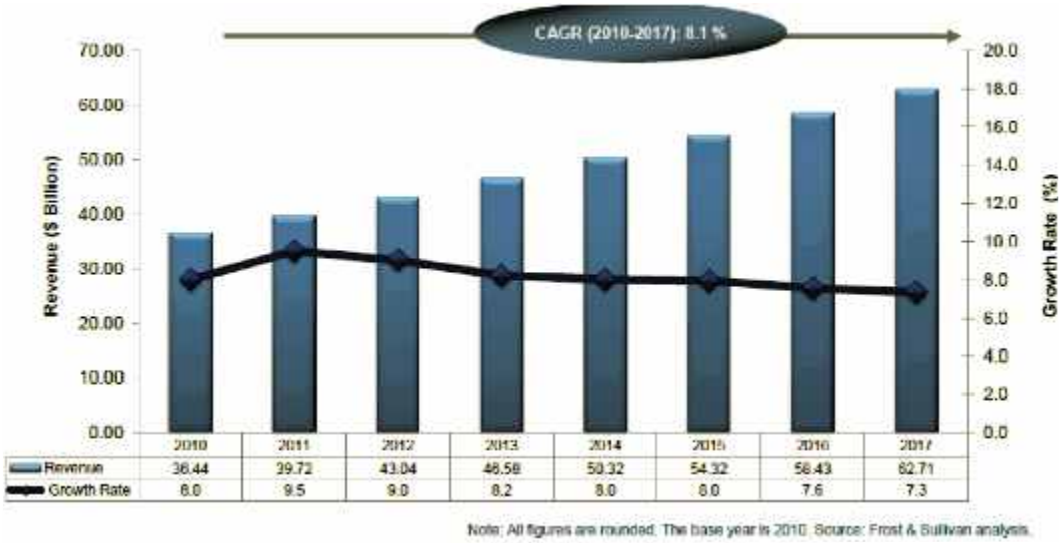
Increased access for the first time to low-cost generic treatment options in the areas of epilepsy, migraine, and immune system disorders is driving growth in the generic pharmaceuticals market. Therefore, the strong political will of both the public and private healthcare sector to curb the rising costs of healthcare will fuel the growth of generics significantly.

The European Generic Pharmaceutical Market

The revenue of the Europe generic pharmaceuticals market was USD 36.44 billion in 2010. The market is expected to reach USD 62.71 billion in 2017, at a compound annual growth rate of 8.1 % from 2010 to 2017.

Chart 4 shows the Forecast for European Generic Pharmaceutical Market 2010-17

Chart 4: Forecast for European Generic Pharmaceutical Market 2010-17



Note: All figures are rounded. The base year is 2010. Source: Frost & Sullivan analysis.

Top 5 European generic markets, namely Germany, the United Kingdom, France, Spain, and Italy account for nearly 80.0 % of the European generic pharmaceuticals market valued at USD 21.68 billion which represents 50.0 % of the volume of medicines but just 18.0% in terms of value.

According to EGA, generic medicines in Europe have generated savings of €30.00 billion excluding those made from the stimulation of competition with the pharmaceutical sector as a whole.

In terms of value, Germany is the largest market with a share of 27.0 % in the European generic pharmaceuticals market, closely followed by the United Kingdom with a market share of 25.0% with growth rates of 6.0% each. On the other hand, though Spain and Italy account for smaller market shares of 4.2% and 2.7%, these markets present remarkable growth rates of 18.0% and 22.0% respectively.

Germany and the United Kingdom are the two most developed generic markets constituting shares of 64.0 % and 60.0 % respectively in terms of volume penetration and accounting for more than half of the total generic pharmaceuticals market in Europe. However, less mature generic pharmaceuticals markets such as Spain and Italy present market shares of 29.0 % and 28.0 % respectively with regards to volume penetration.

Regulatory Environment in Europe

Europe is a highly fragmented market with country-specific regulations, making it quite challenging for generic companies in terms of transparency.

Chart 5 shows a Snapshot of the Regulatory Environment in Europe

Chart 5: Snapshot of the Regulatory Environment in Europe

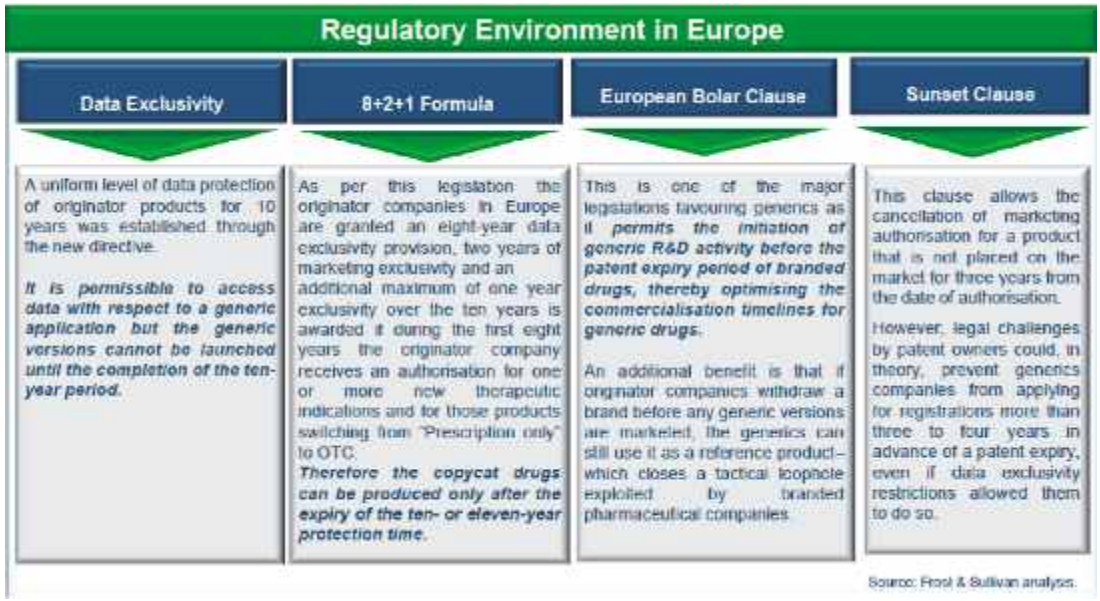


Chart 6 compares the Regulatory Policies of the Generics Markets in Europe

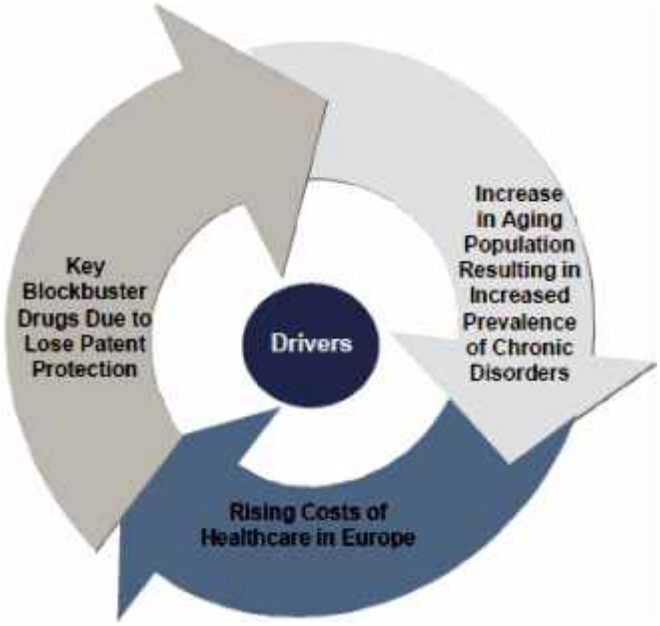
Chart 6: Impact of Regulatory policies

Policies	Germany	United Kingdom	France	Spain	Italy
Reference pricing					
Patient co-payment					
Generic prescribing					
Generic substitution					
Time delay in market access					

High → Low

Source: Frost & Sullivan analysis

Key Drivers for the European Generic Pharmaceutical Market

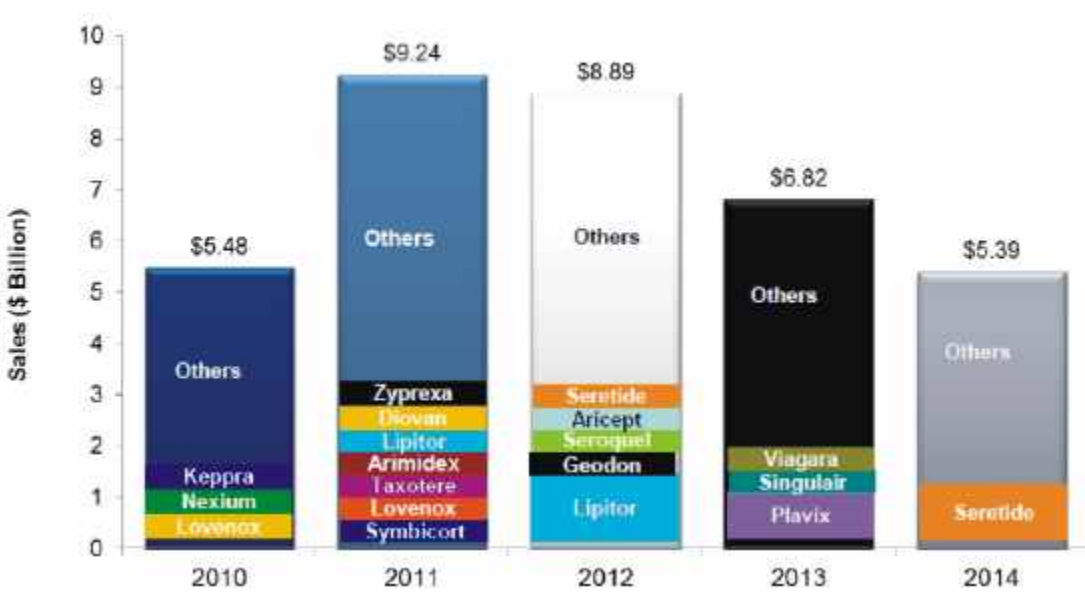


Blockbuster Drugs going Off-Patent

In Europe, nearly 40 % of the patent protected product sales will be available to generic competition between 2010 and 2014.

Chart 5 shows the Sales Value of Drugs Exposed to Generic Competition in Europe

Chart 5: Sales Value of Drugs Exposed to Generic Competition (Europe), 2010-2014



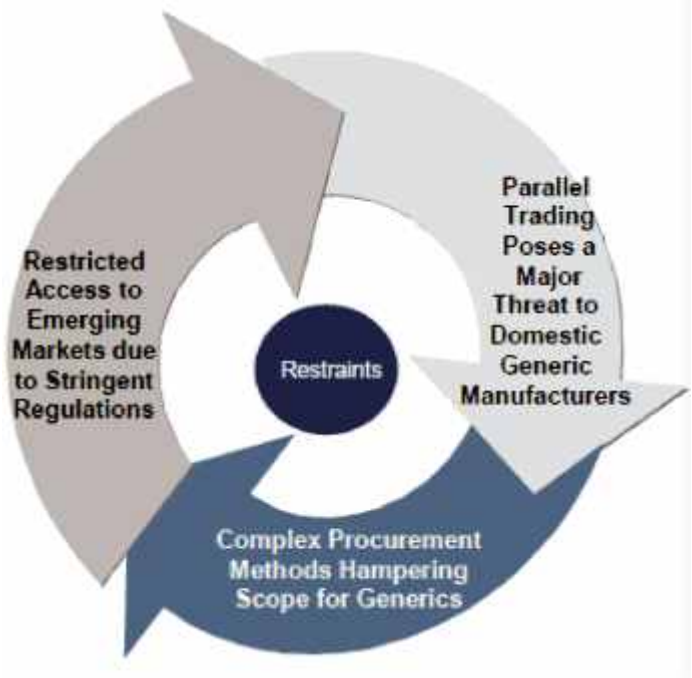
Rising Costs of Healthcare in Europe

The growing cost of healthcare is certain with the increasing aging population and changing lifestyles; drug expenditure is forecast to increase by 5 % annually over the next three to five years. In Europe, medicines account for 10.0 % of the healthcare budget of which generic drugs comprise roughly 1 to 2 %. The extent of penetration of generic medicines is only 50.0 % by volume in Europe to date. According to EGA, generic drugs can currently generate savings of €30.00 billion Therefore increased utilisation of generic medicines will work out to be a promising solution to compensate for the rise in healthcare expenditure, without compromising on health.

Increase in Aging Population Resulting in Increased Prevalence of Chronic Disorders

One-sixth of Europe's population (16.6 %) is 65 years and above and one out of every 25 citizens in Europe is 80 years and above In Western European countries such as France, Germany, and the United Kingdom, approximately 20 to 25 % of the population is above 60 years of age, with high prevalence rates of chronic diseases like cardiovascular disease, central nervous system disorders, diabetes, and other serious illness. Italy has the highest aging population with one out of every five Italians above 65 years of age. This places pressure on the healthcare providers to look out for cost- effective alternatives in the long run in the form of cheap generic drugs in Europe.

Key Challenges for European Generic Pharmaceutical Market



Restricted Access to Emerging Markets due to Stringent Regulations

Market access is a core issue faced by generic manufacturers as Europe still remains a complex market in terms of transparency, delaying the time of pricing and reimbursement approvals and granting of marketing authorisation.

According to the survey conducted by EGA, the variables which affect market access include a) the need for a MA to apply for price; b) the time for approval of price after granting of MA; c) prevention of generic MA due to SPC period; d) naming of the generic product; e) time for approval of generic reimbursement; f) conditions for generic medicines to be interchangeable.

With the exception of Germany and the United Kingdom who have a free pricing system, there is a significant time delay for market access in all other countries. Emerging generic markets such as Spain and Italy experience a delay of 150 and 130 days for price and reimbursement approval. This is the root cause for low levels of generic penetration in these markets.

Complex Procurement Methods Hampering Scope for Generics

A major threat to the generic medicines industry is the change in the method of procurement of generic drugs to tendering system bidding for the lowest priced drug. This favours the low cost overseas generic manufacturers, India and China, who export their APIs and generic formulations at a marginal cost, leaving the European generic participants with large inventories. This practice could have a deleterious impact in the long run as drugs are chosen based on the lowest price, surpassing attributes such as quality and importance of health to patients. The extremely low profit margins to distributors compel them to acquire pharmacies, thereby changing their role in the supply chain.

Parallel Trading Poses a Major Threat to Domestic Generic Manufacturers

Parallel trade is a common practice in Europe and involves importing drugs from cheap and less regulated markets like India and China and selling them at a relatively higher price in Europe. The parallel trade market in Europe was estimated to be worth USD 7.40 billion in 2006 and growing in double digits. Though the government traditionally encouraged this practice as it served as a cost-cutting measure, the actual beneficiaries are the companies that buy and resell these drugs at a cheaper cost. This led to quality and safety concerns due to improper handling, packaging, and selling of counterfeit drugs. The branded pharmaceutical companies are the major sufferers, yet this practice has not spared even the generic companies, resulting in increased pricing pressure.

Key Generic Pharmaceutical Markets in Europe

Germany

The revenue of the German generic pharmaceuticals market was USD 8.80 billion in 2010. The market is expected to reach USD 15.01 billion in 2017, at a compound annual growth rate of 7.9 % from 2010 to 2017.

In Germany, the reference pricing system references prices from other EU markets. Pharmaceutical Companies set their own prices Therefore there is no delay in market entry of generics. The Bonus-Malus rule allows health insurance schemes to fix daily cost-of-therapy limits for drugs that have substantial sales and ranges of clinically comparable therapies. Ex-factory prices of drugs including reimbursed products are not directly regulated whereas distribution margins are regulated. The listed retail price of a particular reimbursed product is the same throughout the entire German territory. Only a percentage of the MRP of drugs is reimbursed; generally patients contribute to their pharmaceutical expenses.

The German government encourages generic prescribing through incentives for physicians and pharmacists. As per the substitution rule under the German Healthcare Reform (GMG), pharmacists are free to regulate the substitution choices. Price competition is relatively low in Germany due to oligopoly with the top three participants grabbing a significant market share. Since Germany is a branded generic market, maintaining a comprehensive product portfolio and aggressive brand promotion through adequate sales force are pre-requisites.

Future Prospects

The German government is still trying to increase savings through regulations favouring the generic pharmaceuticals market. Blockbuster drugs worth USD 110 billion are set to lose patent protection during the forecast period. Parallel imports from cheaper markets pose a challenge to the existing participants.

United Kingdom

The revenue of the United Kingdom generic pharmaceuticals market was USD 5.40 billion in 2010. The market is expected to reach USD 9.61 billion in 2017, at a compound annual growth rate of 8.6 % from 2010 to 2017.

Reference pricing is used as a control mechanism. The government takes charge of the price controlling mechanism in the United Kingdom. According to this system, profits are controlled based on sales rather than directly fix prices. A new category M of generic medicines the basic prices of which reflect the average manufacturers' market prices after discount, was introduced under Part VIII by the April 2005 Drug Tariff.

Category M allows the members of the British Generic Manufacturers Association to set the price of generic medicines, provided that the designated price does not exceed the price of the innovator product at the time of patent expiry. Reimbursement rates of Category M pharmaceuticals are calculated based on weighted average price (charged by manufacturers after discount).

From 1 February 2009, the prices of the prescription drugs to NHS were reduced by 3.9 % in accordance with the Revised Pharmaceutical Price Regulation Scheme (PPRS) and by another 1.9 % in January 2010. Further price cuts of 1.9 % in January 2010 were imposed, not contingent on the growth of the drugs bill - plus increases of 0.1 % in January 2011, 0.2 % in January 2012 and 0.2 % in January 2013. Generic substitution was introduced in January 2010.

As per the value-based pricing enforced in the market, it is expected of the drug company to submit clinical trial evidence stating that their drug is more effective than the existing drugs in the market at the time of fixing the price of a new drug candidate. Strong incentives for generic prescribing and dispensing fuel the growth of the generic pharmaceuticals market. Physicians are trained to prescribe generics by INN and the substitution rights for pharmacists are well established here. The strict budget levels for NHS doctors to curb the healthcare expenses favour generics widely with more than 55 % of NHS prescriptions constituting generics.

Future Prospects

With the introduction of the Generic Substitution System in 2010, high levels of INN prescribing and the rigorous healthcare budgets of NHS, the generic pharmaceuticals market of the United Kingdom is on a growing curve. However, the high levels of generics penetration in the United Kingdom market presents relatively lower growth rates than those of the emerging markets of France, Spain, and Italy.

France

The revenue of the French generic pharmaceuticals market was USD 4.20 billion in 2010. The market is expected to reach USD 12.14 billion in 2017, at a compound annual growth rate of 16.4 % from 2010 to 2017.

Medicine prices in France are cheaper when compared to those of other EU countries. Generic medicines need to be priced at least 30.0 % less than originator drugs. RPS has led to a reduction of prices by originator companies to 65.0 %, thereby nullifying the competitor price advantage of generic companies. There is a lack of incentives for physicians and patients for generic prescribing. Physicians generally prefer prescribing branded drugs to generics. As per the Jacob's Law, pharmacists are given a maximum of 15.0 % discount for generic substitution by generic companies in 2007. Though this policy attracted the pharmacists, it did not benefit the patients. The average time delay for P&R approval after grant of marketing authorisation (MA) is 75 days.

Future Prospects

With targeted savings of €500.0 million in 2011 due to the continued promotion of generics and several blockbusters coming off patent, significant growth in volume sales is expected while pricing pressure due to price cuts and widening price differentials will reduce value growth. Pharmacists have set substitution goals of 70.0 % for each molecule and this is set to fuel the growth of generics in future. Smaller generic companies who are unable to offer large discounts to pharmacists under the Jacob's Law will tend to seek the support of big generic companies.

Spain

The revenue of the Spanish generic pharmaceuticals market was USD 2.20 billion in 2010. The market is expected to reach USD 7.19 billion in 2017, at a compound annual growth rate of 18.4 % from 2010 to 2017.

Reference pricing is calculated based on the average prices of the three cheapest drugs and is set close to the level of marginal cost. Pricing rules established a minimum price difference between the originator and generic brands which did not appeal much to the patients and inhibited the demand for generic medicines. The new medicines law governing generic substitution by pharmacists provided strong incentives for originator brands to reduce their prices to the level of RP, thereby eroding the price advantage of generic drugs.

There were very few incentives to physicians (2.0 % of gross salary) for generic prescribing. They are not obliged or stimulated to INN prescribing. Pharmacists are financially penalised for dispensing generic drugs. Patient co-payment for reimbursed drugs is based on their income status. The employed (40.0 %), civil servants (30.0 %), patients with chronic disorders (10,0 %), and patients above 65 years are exempted from payment. The average time delay for approval of P&R after MA is 150 days. The Spanish generic market is a low volume generic market.

Future Prospects

Improvements within the Spanish Medicines and Health Products Agency and additional funding will help speed up the generic drug registration procedures, boosting their availability. Measures to promote INN prescribing are on the rise. The incorporation of the Bolar Provision in the new medicines law encourages the experimental use of branded drugs prior to patent expiry. Though the cost containment provisions of the new medicines law stand to benefit the generic participants, the branded companies get price concessions at the expense of generics.

Italy

The revenue of the Italian generic pharmaceuticals market was USD 1.09 billion in 2010. The market is expected to reach USD 4.37 billion in 2017, at a compound annual growth rate of 21.9 % from 2010 to 2017.

Reference pricing and the establishment of re- imbursement price ceilings at the level of the cheapest generic has restricted the commercial opportunities for generic drug makers in Italy. There are very few incentives for physicians and pharmacists to prescribe and substitute generics. INN prescribing is not practised. Both physicians and patients have a strong affinity for brands rather than generics.

Innovator companies are willing to slash their prices in a bid to maintain volumes and limit patent exposure to reference-based co- payments. Patient co-payment is not widely practised. The average time delay for P&R approval after MA is 135 days. Therefore, the generic pharmaceuticals market is poorly developed in Italy, with brands dominating the market.

Future Prospects

Aggressive cost containment strategies pursued by regional authorities in Italy are expected to fuel the growth of generics. The introduction of therapeutic reference pricing and making INN prescribing mandatory in some regions despite the strong opposition will drive further growth. Initiatives to increase awareness among people and develop guidelines for physicians and pharmacists will favour the cause of generics. The Italian Medicines Agency, AIFA, aims to increase the generic pharmaceuticals market share to 20.0 %.

Conclusion

With increasing healthcare expenditure, developed countries have taken an interest in creating policies for generic medicines. Emerging markets in Europe such as Spain, Italy and France have also seen generic penetration increase steadily. However, time delay in pricing and reimbursement approval after the granting of marketing authorization needs to be rectified as early as possible to facilitate early market access for the generic companies without losing out on a significant chunk of business.

Industry's Voice for Policy Change

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