

Global Pharma Market Scenario: Drug Shortages, Challenges & Opportunities

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Abstract-The pharmaceutical market worldwide, after experiencing a slump during the past 2-3 years, is now in its recovery period. Decline in global pharma market was largely due to the economic slowdown, and further aggravated by patent expiry of key blockbusters together with saturation in key pharma markets, such as the US and Western Europe. Meanwhile, Pharma markets in some developing regions, like Asia and Latin America have been continuously witnessing robust growth rate for the last few years on account of increasing prevalence of diseases, rising healthcare spending, and increasing affordability. According to latest research “Global Pharmaceutical Market Report & Forecast: 2012-2017”, The global pharmaceutical market is expected to grow at a Compound Annual Growth Rate (CAGR) of 5% during 2011-2017, exceeding sales worth US\$ 1.1 Trillion by 2017. The statistics proves that we are witnessing a huge transition in pharmaceutical market and the market is shifting from well regulated markets like US, Europe & Japan to emerging markets like India, China, Brazil, Mexico and Russia etc. Which will be discussed throughout this article and the key areas are enlightened where challenges as well as huge revenue generating pharma sectors are awaiting for pharma companies. This article illustrates the upcoming expectations of pharma markets in various regions with special emphasis on sterile products like injectable, total parenteral nutrition, oncology product and biological product which are facing shortages worldwide.

Keywords: Global Pharma Market, Drug shortages, Sterile Injectables, Indian Pharma Market Scenario, FDA Drug Shortage etc.

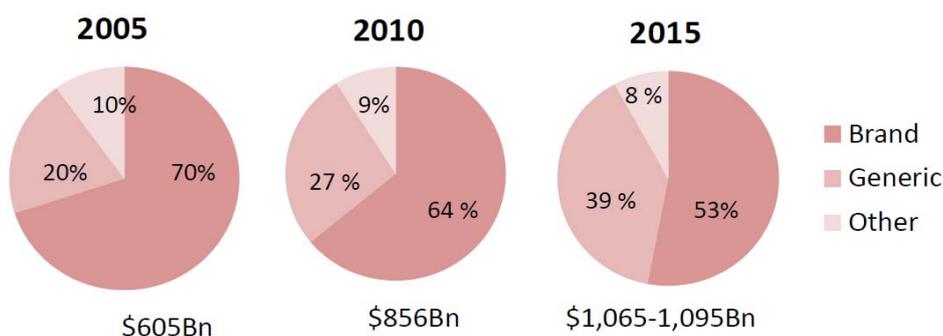
INTRODUCTION

According to latest research “Global Pharmaceutical Market Report & Forecast: 2012-2017”, The global pharmaceutical market is expected to grow at a Compound Annual Growth Rate (CAGR) of 5% during 2011-2017, exceeding sales worth US\$ 1.1 Trillion by 2017¹. The research identifies that sales of generic drugs will emerge as the most prominent segment of the pharma market during the forecast period, indicating large opportunities for generics manufacturers to tap¹. Spending on medicines which was estimated at \$856 billion in 2010, is expected to reach nearly \$1,100 billion in 2015, reflecting a slowing growth rate of three-six per cent over the five year period compared to 6.2 per cent annual growth over the past five years².

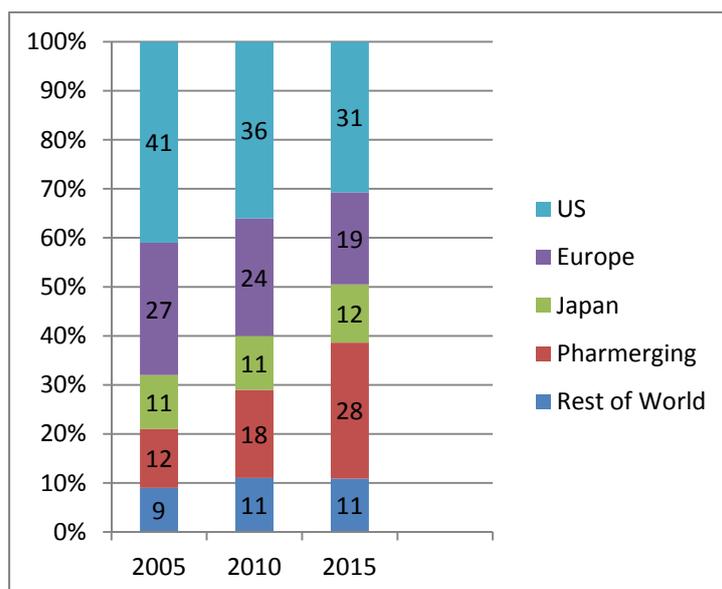
Shifting Pattern in Global Pharma Market

The pharma industry is growing at a rapid rate in emerging countries, such as India, China, Brazil, Russia, among others, while a slowdown in the growth has been encountered in the US and Western European countries^{Error! Reference source not found.}. A distinct shift is expected in the market shares across the globe, with the US and Europe share of global spending declining Meanwhile, 17 high growth emerging markets (pharmerging) including China, India, Brazil, Russia and Mexico will contribute 28 per cent of total spending by 2015, up from only 12 per cent in 2005 The next five years will also see an accelerating shift in spending toward generics, rising to 39 % of spending in 2015, up from 20 % in 2005 (See **Graph: 1 Shifting pattern in Global Pharma Markets: 2005-2015**)³.

Spending by Segment



Source: IMS Market Prognosis, Apr 2011

Graph: 1 Shifting Pattern in Global Pharma Market 2005 - 2015

Source: IMS Market Prognosis, Apr 2011

Table 1: Major Patent expiries by country by year

Protection expiry year	US		JAPAN	UK	FRANCE	GERMANY
2011	Lipitor Advair Diskus Zyprexa	Levaquin Xalatan Femara	Actos	Lipitor Zyprexa Clexane Xalatan Femara	Zyprexa Xalatan Femara	Clexane Zyprexa Xalatan femara
2012	Plavix Seroquel Singulair	Actos Lexapro Diovan	Seroquel	Seroquel Singulair	Singulair	Seroquel
2013	Oxytocin Aciphex	Zometa Xeloda	Aricept Diovan Plavix	Seretide Xeloda	Seretide Xeloda	Xeloda
2014	Nexium Cymbalta	Copaxone Celebrex	Abilify	Abilify Celebrex	Abilify Celebrex	Abilify celebrex
2015	Abilify Gleevec	Namenda	Alimta Spiriva	Spiriva Alimta	Alimta Spiriva	Spiriva Alimta

Source: IMS market Prognosis; Apr, 2011

Key blockbuster Patent Expiration

The other hand, share of patented brands which accounted for nearly 70 per cent of global pharmaceutical spending in 2010 are expected to decline to 53 per cent in 2015, on account of patent expiries, mainly in the developed markets. (See Table 1: Major Patent expires by country by year)

Market Scenario of Sterile Injectables Worldwide^{4,5}:

Injectables are specialized and niche area within the pharmaceutical industry due to the high complexity involved during development and manufacturing. Sterile injectable products have major role in treating disease which includes anaesthesia, critical care, anti-infectives, renal care, infusion therapy, enteral & parenteral nutrition and oncology⁴.

The overall size of the injectable market during 2009 was approx US\$ 200 bn. This has grown further by 10% to US\$ 220 bn in 2011 with generic penetration being 15%. In the

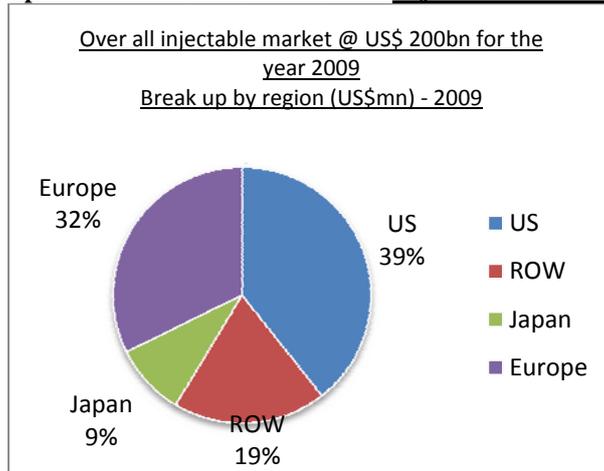
injectable group, the segments of biologics and oncology are relatively more lucrative offering higher upside. (See Graph 2: Market Scenario of Sterile Injectables Worldwide, Graph 3: Segmental Breakup – Worldwide Sales 2009 US\$ 763 bn)

US, being the world's largest pharma market, also accounts for the largest chunk of the overall injectable space. During 2011, US had 38% share in the injectable market of which generic penetration was at US\$ 5 bn. It is expected that by 2015 roughly 75 products worth US\$ 16 bn could face the entry of generics for the first time. It is also estimated that US generic injectable sales would grow at a CAGR of 10% in the period 2012-2015.

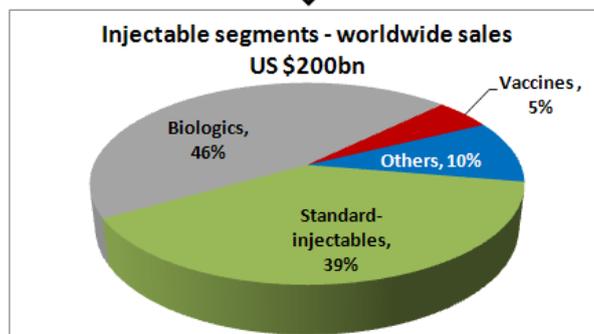
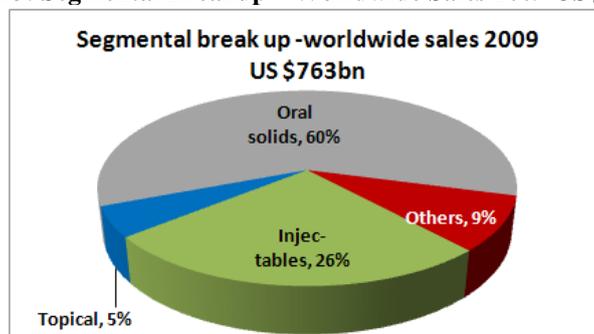
India Market Scenario^{4,5}

The Indian pharma market is forecasted to grow at a CAGR of 15.9 per cent (± 4.0 per cent) between 2010 and 2015, doubling in five years to Rs. 119677 crore (See Graph: 4 India Pharmaceutical Market Forecast).

Graph: 2 Market Scenario of Sterile *Injectables Worldwide*



Graph 3: Segmental Breakup – Worldwide Sales 2009 US\$ 763 bn



Graph:4 India Pharmaceutical Market Forecast



According to IndiaVenture Advisors, the total Indian market for injectables been estimated at about Rs 6,500 crore for FY09. The total domestic injectables market is estimated at about \$450 million and was estimated to have grown at more than 20 percent in the last three years. The Hospira-Orchid and Pfizer-Strides or Pfizer-Claris deals indicate that the injectables and parenterals market is in tumult.

"Low cost of production, and availability of low-cost scientific manpower are the core strengths of the Indian market which force MNCs to look for production partners to supply their injectable drugs in India and other parts of the world."

Major markets for injectables/parenterals include vaccines, anti-infectives, oncology, biological, and nutritional. Apart from these, several other drug classes such as insulins, drugs for pain management, CNS (Central Nervous System) drugs, and GI (Gastro Intestinal) drugs also contribute considerably to the injectable drugs market.

Growth Areas^{5, 6, 7, 13}

Oncology drugs form one of the largest and fastest-growing sectors of the global generic injectable market, highlighting the numbers. Annual sales of the global generic injectables sector were \$10-12 billion in 2008, according to IMS Health, with injectable oncology medicines accounting for about 30 percent. Additionally, injectable oncology medicines worth \$9 billion in annual sales are expected to lose patent protection by 2015.

The other area that will drive growth in the Indian market is the antibiotics segment, as the injectable antibiotics market in India has shown robust growth in the last four to five years. The domestic injectable antibiotics market is worth \$425 million and has been growing at a Compounded Annual Growth Rate (CAGR) of 21 percent in the last three years.

The market for injectable in the antibiotics segment and particularly for cephalosporin has been growing significantly and there is a huge opportunity in the Indian market itself. The other market with huge potential is multivitamin injectables. The size of the non-biological injectable market is estimated to reach about \$80 to \$100 billion in 2015, out of which generics could account for

about \$35 billion. It was estimated that from 2006 to 2009 patents expired on non-biological injectables worth \$15 billion.

Indian companies are able to manufacture and supply high volumes of parenteral drugs to the world market through Joint Ventures with MNCs / NGOs / international health organizations such as WHO, UNICEF and so on. More such Joint Ventures are expected in future, which will shape the injectable/parenteral market.

In recent past there has been double digit growth in market segments where injectables and parenteral are largely used such as vaccines, anti-infectives, oncology, biologic therapy, nutrition, pain management and so on. Most of these markets are growing at a rate close to or more than 20 percent, except for injectables in the antibiotic and pain management segment, which are growing at a rate close to 15 percent. These market segments are expected to grow at a similar rate in the coming three to five years, which will drive the usage of parenterals,

In 2009, approximately 390,000 patients in the major markets of the US, EU and Canada used parenteral nutrition products, accounting for total product sales of \$1.3b. Through 2014, the total number of parenteral nutrition users in will rise by 10.0% per year to 628,000 and sales will expand by 11.3% per year, reflecting only nominal annual price increases.

Sterile Injectable Drugs Shortage^{8, 9, 10}:

The Food and Drug Administration (FDA) reports that, in 2010, there were 178 drug shortages recorded at the Agency. Currently, shortages are concentrated in the area of sterile injectable drugs, 132 of which are now in shortage. In 2011, FDA has continued to see an increasing number of shortages, especially those involving older sterile injectable drugs, including cancer drugs, anesthetics for surgery, drugs for emergency medicine, and electrolytes for intravenous feeding.

Approximately 40% of drugs under shortage in US in past five yrs. were sterile. Especially in U.S shows that the maximum number of drug shortages includes sterile injectable drugs which are the key factor and reason for coming up with this article. (*Graph: 5 Shows Trends in the Total Number of Drug Shortages and The Number of Shortages of Sterile Injectable Drugs*)

Graph: 5 Trends in The Total Number of Drug Shortages in U.S

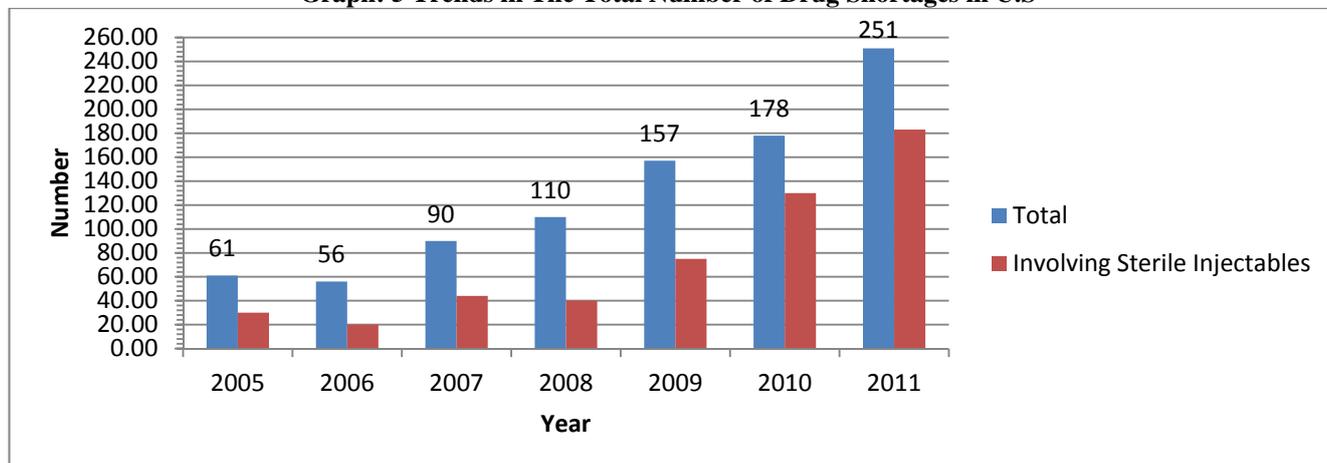


Table: 2 (Drug Shortages Reported Annually)

Drug Shortages Reported Annually by FDA Shortage Program and American Society of Health-System Pharmacists/University of Utah Drug Information Service				
Year	ASHP/UTAH Drug Shortage	FDA Drug Shortage	FDA Drug Shortage, Sterile Injectables	FDA Percent Sterile Injectables
2005	74	60	30	50.0
2006	70	55	25	45.5
2007	129	92	42	45.7
2008	149	110	40	36.4
2009	166	157	75	47.8
2010	211	178	132	74.2
2011	---	251	183	72.9

There are drastic drug shortages, which have been reported by various agencies in past few years (*Shown in Table 2*). The University of Utah DIS reported 211 shortages in 2010 and 166 shortages for all of 2009. DIS drug shortages declined from 120 in 2001 to 58 in 2004, and have risen steadily from 74 in 2005 and 70 in 2006 to 166 in 2009. Additional information on FDA's data on reasons for drug shortages is provided in the companion FDA report, "A Review of FDA's Approach to Medical Product Shortages"¹¹.

CONCLUSION

Based on the statistical data obtained from various sources and pharma reports, it is clear that there are huge opportunities for Generic manufacturer to tap in the worldwide pharma market especially in Pharmerging markets, as the key blockbuster drug patents have expired in recent times or going to expire shortly. Economic slowdown is observed in various part of the world, in which Europe and USA are the most affected regions hence it is wiser to invest in emerging market which have been continuously witnessing robust growth rate even in recession period. Also huge opportunities can be seen for pharma companies to work in specialized products like Sterile injectables which includes anaesthesia, critical care, anti-infectives, renal care, infusion therapy, enteral & parenteral nutrition, oncologyetc¹¹.

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