

US Generic Drug Market – A Study on Evolving Trends

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Abstract :- Generic drugs generate a lot of interest in the sector in recent times. There is a lot of competition between generic drugs and brand names in the market. Recently there are growing conditions which hinder the smooth adoption of these medicinal products in the market. This paper will discuss some of the issues which revolve around the generic drug industry.

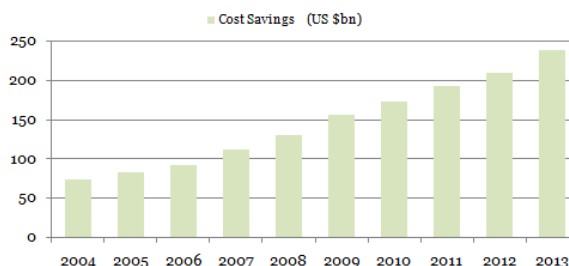
Keywords - About five key words in alphabetical order, separated by comma

I. INTRODUCTION

The US generic drug market has witnessed a transformation over the last three decades. From less than 20% of the total prescriptions, generic drugs now account for the majority of the total prescriptions dispensed in the United States [1]. During 2010-2015, the US generic drug market grew at a CAGR of more than 11% and currently represents a multibillion dollar industry [1]. The biggest catalyst of this industry is the significantly lower price of generics compared to branded drugs. Although generics are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price [1]. This has enabled governments and third-party payers to save billions of dollars in healthcare expenditures and resulted in lower copayments for patients [2]. Other factors such as patent expiration of blockbuster innovator drugs, ageing population and an increasing prevalence of chronic diseases have also acted as catalysts for this market. The article entitled "*Opportunities and Challenges Brought by GDUFA in 2013*" provides a comprehensive insight into the historical and current trends as well as the future prospects of the generic drug market in the United States. This study serves as an exceptional tool to understand the sales trends, volume trends, growth, key segments, competitive structure, regulations, major manufacturer, major distributors, top drugs, manufacturing requirements, opportunities and future prospects of the US generic drug market. This article can serve as an excellent guide for manufacturers, consultants, researchers, marketing strategists and all those who plan to foray into the US generic drug market in any form. Generic drugs are copies of branded drugs, which can only be produced after the brand-name drug's patent has expired [3]. Although they are identical to their branded counterparts (on a variety of measures as described by the FDA), they are priced at significant discounts to the branded price. As generic drug makers go through an abbreviated and less costly process to get an approval from the FDA, prices of generics are relatively lower. (In other words, branded drug manufacturers pass on the high development costs to consumers.) The scenario was different before the Hatch-Waxman Act, which was enacted in 1984. Before 1984, generic drug makers were obligated to go through the same process as branded drugs to receive an approval from the US FDA, which created steep financial barriers to the development of generic drugs [3].

II. THE RISE OF GENERICS

After amendments were made to the law in the favor of generic drug makers, this market saw an influx of new players, which brought generic prices further down. Currently, on average, the cost of a generic drug is 80 to 85 percent lower than the brand name product. As prices declined, usage of generics picked up rapidly. The share of generics out of all the prescriptions filled in the US increased from ~18% in 1984 to nearly 80% currently [1]. This decade has seen branded drugs worth billions of dollars in sales lose patents. In 2012 alone, the sales value of drugs coming off patent was \$33 billion and another \$47.5 billion in sales will come under threat of patent expiry this year [4]. As terrifying as this can be to the ears of pharmaceutical companies, it is just what the doctor ordered for the US health care system, as health care expenditure is rising really fast. In the ten-year period between 2003 and 2012, generic drugs generated \$1.2 trillion in savings to the U.S. health care system.



However, generic prices have been moving up for some time now, which is leading to some serious concerns for the pharmacy retail industry in the form of reimbursement rate pressure (Here's a detailed analysis of this issue). The FDA (Food and Drug Administration has many backlogs on ANDAS (abbreviated new drug applications) [5]. Brand name drugs require long durations combined with expensive trials and research before approval for sale by the FDA [6]. Drugs like EPIPEN are expensive due to lack of cheaper alternatives. One of the main causes is the FDA backlog on presumably better alternatives [7]. One of the major concerns of players in the drug industry is the noticeably fewer approvals of generics by the FDA [8]. The slow approvals threaten the market through high product prices and lower competition. There are growing discussions on how best to solve this issue. The generic drug industry in the United States faces a challenge to remain competitive and also give value to their clients [9]. Brand name companies sometimes engage in unfair practices to lock out generic products longer than necessary [8] (Kantarjian, 2016). The generic drug industry needs to find ways to counter the brand names so as to thrive in the market.

III. THE RISE OF GENERIC PRICES

According to a chapter 2015 RAPS chapter 15 [3], a drug product and pricing information provider, out of a research sample of 4421 drug groups, 222 drug groups increased in price by 100% or more (between Nov'13 and Nov'14). There are also some extreme cases (17 drug groups) where price increases of more than 1000% were seen. One such product is tetracycline, which is commonly prescribed for bacterial infections [10]. During the same period (between Nov'13 and Nov'14), it's per tablet price increased from \$0.0345 to \$2.3632 [11]. That is a 67-fold increase in one year! But, why are generic drug prices increasing at such high rates?

In 2009, generic drug markets were saturated and projections looked dull. To avoid falling into losses, generic drug makers began to consolidate through mergers and acquisitions to achieve the scale needed to maintain profitability. Typically, when a branded drug loses patent protection, multiple generic manufacturers produce the drug and compete on price. But post-industry consolidation, fewer generic manufacturers are applying to the FDA for permission to produce those drugs [12]. With substantially fewer manufacturers producing a particular generic drug (in some cases only 2 or 3 makers), generic prices have crept up with time [3]. There is a steady increase in the price of generics in the market [6]. These price increments tend to hurt many parties in the supply chain [5]. Some consumers will reject medication due to high prices. Physicians are also finding trouble in looking for alternative more cost friendly prescriptions. Also, there is a growing trend of consolidation of wholesalers dealing in pharmaceutical drugs. Many pharmaceutical companies are merging so as to be more competitive in the market [4]. Some reports indicate that large drug wholesalers benefit illegally from consolidation through price manipulation in the industry [3].

IV. CONCLUSION

Evidently, generic drugs face numerous challenges before they enter the market. Both the FDA and other brand names offer challenges to them. However, generic drugs are critical to both the suppliers and final consumers. All stakeholders should strive to find better ways to improve the generic drug industry. Consolidations within the pharmaceutical industry, and supply shortages due to various issues have played a major part in generic price inflation. As a result, some retailers have even dropped drugs from their discount generic drug programs. However, one way the industry is responding is by creating a tiered pricing system for generic drugs that would require members to pick up more of the cost. This pricing system is still in its formative stages and might take a while before it helps bring generic prices back down (if at all). Until then, retailers would have to devise their own strategies, including increased spending on acquisitions.

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