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Price Cut and Its Impact on Pharma Industry

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Certificate

This is to certify that Pramod Patidar has undergone summer training in Cadila Pharmaceutical ltd., Ahmadabad from 18th April to 9th June, 2012

The candidate carried out all the studies related to summer training herself. Her approach to the studies has been sincere, scientific, and analytical. This summer training in partial fulfillment of the course requirement is recommended for the award of Post Graduate Diploma in pharmaceutical Management.

I wish her success in all future endeavors.

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1. EXECUTIVE SUMMERY

An era where the market competition has reached new height due to government policies and stringent regulation in pharma industry, companies are strategizing and implementing innovative and novel strategies so as to penetrate the market, a race for increasing customer base, and the lead for maintaining a position in market and enhance Profit margin, the bottom-line of any business. Pharmaceutical companies are finding the new ways to compensate their profit margin with market dynamics.

This Research paper summarizes the results of our global pharmaceutical industry analysis and is intended to increase awareness of the general public – investors, policy makers, and managers, employees of the companies – about its current development of strategy against pricing pressure, either due to Government policy or trade competition, and changing demographic with implementation of new pricing strategic initiative in pharma industry. This research also suggest that the future perspective of pharma industry with reference to the market dynamics.

2. BRIEF PROFILE OF COMPANY

Cadila Pharmaceutical ltd. Ahmadabad

Cadila Pharmaceuticals Ltd. is one of the largest privately held pharmaceutical companies in India, headquartered at Ahmadabad, in the state of Gujarat. Over the last five decades, it has been developing and manufacturing pharmaceutical products and selling and distributing these in over 50 countries around the world. An integrated healthcare solutions provider with pharmaceutical product basket, it caters to over 45 therapeutic areas that include cardiovascular, gastrointestinal, analgesics, haematinics, anti-infective and antibiotics, respiratory agents, ant diabetics and immunological. The company focuses on providing high quality, appropriately priced products to its customers and supports all these with dedicated customer service. Cadila Pharmaceuticals has a multicultural, multilingual and multinational workforce of more than four thousand employees including over two hundred people outside India in forty-nine countries of Africa, CIS, Japan and USA.

The company has one of the best Research and Development (R&D) setups in India, manned by more than three hundred and fifty scientists and engineers from various disciplines including biology, pharmacology, clinical research, chemistry, toxicology, photochemistry and different disciplines of engineering. The company also participates in Public-Private partnerships for developing diagnostic, preventive and curative pharmaceutical and diagnostic products.

Cadila Pharmaceuticals is the first Indian company to get IND approval by USFDA for clinical trials to be conducted in India. Subsequently, the company has filed four more INDs with USFDA. Of the five INDs filed, one is for pulmonary tuberculosis; the trial is supported by Department of Biotechnology, Govt. of India. The remaining four are for various types of cancers, e.g., Lung Cancer, Prostrate cancer, Bladder Cancer and Melanoma. Thus all the INDs are for providing solutions to major global health care problems. The clinical trials on prostate cancer, Lung cancer and Bladder cancer are supported by Department of Science and Technology to encourage innovations.

The company has state-of-the-art manufacturing facilities conforming to the most stringent international cGMP norms vis-à-vis WHO-GMP, WHO, Geneva (GDF site for Anti- TB),

TGA Australia (PIC/S), USFDA, UK- MHRA, MCC-South Africa, ISO 9001 and ISO 14001. Spread over hundred acres of land, Cadila Pharmaceuticals' manufacturing facility at Dholka is the cynosure of all eyes, well equipped with world-class production facilities. The company's two Active Pharmaceutical Ingredients units at Ankles war manufacture a wide-range of APIs and intermediates including three USFDA certified products. The manufacturing facility at Samba, near Jammu, started its commercial operations in August 2006. The first overseas formulation manufacturing facility of Cadila Pharmaceuticals Ltd. has commenced its operations in Ethiopia.

Vision

"Our vision is to be a leading pharmaceutical company in India and to become a significant global player by providing high quality, affordable and innovative solutions in medicine and treatment."

Mission

"We will discover, develop and successfully market pharmaceutical products to prevent, diagnose, alleviate and cure diseases.

We shall provide total customer satisfaction and achieve leadership in chosen markets, products and services across the globe, through excellence in technology, based on world-class research and development.

We are responsible to the society. We shall be good corporate citizens and will be driven by high ethical standards in our practices."

Champion Brands

Envas

Cadila Pharmaceutical makes India's No. 1 ACE inhibitor, Envas, Which has been listed among the country's top 50 Pharma Brands, across all categories. Other CPL brands in top 300 brands of Indian Pharmaceutical Industry are Aciloc and Haem-Up.

Aciloc

A Ranitidine preparation, Aciloc is one of India's best selling brands in this category.

Lmx, Symbiotik, Clax

Antibiotics with live Lactobacilli combination, lmx, Symbiltik, Clax are the first brands of its kind in India, for which Cadila Pharmaceuticals has applied for a worldwide patent. This unique innovation has already been granted Indian, UK and US, Eurasian & Sri Lankan patents.

Rabeloc, Aciloc RD, Zaso, Mixulin, Montelast and Nodan are some of the best selling brands in their categories.

CPL is the first company in India to introduce **Rabeprazole and Fosniopril** formulations.

3. INTERNSHIP DETAIL

Objective:-

To study the strategies adopted by Pharmaceutical Company against price cut (government and trade) for drug Products and explore the same for Cadila Pharmaceutical**.**

Research Objective:-

1**.** To explore the strategy adopted by Pharmaceutical Company against price cut

A. Government Price cut for drug product

B. Trade Price cut for drug product.

2. To suggest Strategy for Cadila Pharmaceutical against this price cut of drug products.

Methodology:-

Research Design: - Descriptive study design

Sampling Method: - Judgmental Sampling

Data Source: - Secondary data

Data collection Technique:- Using available information

4. INDUSTRY OVERVIEW

The pharmaceutical industry is complex, dynamic, and highly globalized, with many pharmaceutical companies operating in multiple countries. The technologies leading to drug discovery and development are at the limits of human knowledge. The huge size of the companies and the complexities of their processes and technologies presents many organizational and management challenges. The development and management of the distribution system is **highly costly**. Adding to the international nature of the industry, there is a continued trend toward **outsourcing** various stages of the development and production of a single pharmaceutical product, including intermediate and active ingredient process development; as a result, a single finished product may be the result of materials manufactured in more than one country. In addition to its global aspect, the pharmaceutical industry continues to be **characterized by high R&D expenditures and extensive regulation of its products compared with other manufacturing sectors**.

However, excellence in managing all these aspects of the industry is a necessary Condition for the survival of the global pharmaceutical companies, the uncertainty of the discovery process and the potentially huge returns from the discovery of a single drug, success in the industry depends on a high measure of luck. Much of the thinking about business strategy in the industry is how best to cope with this uncertainty.

The highly skewed nature of the returns from the drug discovery and development process means that a single drug can deliver corporate success at least in the short to medium term. But this aspect of dynamic industry fails **the diversified product portfolio strategy**. Returns from pharmaceuticals are highly volatile. For the established pharmaceutical companies the response to the discovery uncertainties has been to build scale through **mergers and acquisitions** so that the latter stages of their product pipelines have at least a handful of highly prospective blockbuster drugs.

5. CURRENT TRENDS AND SCENARIO

The global pharmaceutical market in 2012 is expected to grow by 8.6 percent and will reach at a level of $990 billion USD, driven by stronger near-term growth in the US market. In 2011, the pharmaceutical market has grown meager to 5.1 percent with market size of $920 billion USD. With the global pharmaceutical market registering sluggish growth (4-6%) multinational companies have shifted their attention on emerging markets like India, China Brazil and other emerging market which grow at double digit rate of round 13-15% in 2011. Economic growth increasing healthcare expenditure and improved intellectual property frame work has made these emerging countries as attractive destination.[1]

Currently, the global pharmaceutical market is dominated by US, which accounts for about 28 percent of global sales in 2009 followed by the EU accounting for roughly 15 percent and Japan accounting for 12 percent. Together, these three regions represent nearly 55 percent of the global market.

With global increase in expenditure on healthcare, Governments around the world are grappling to arrive at solutions for health account deficits also the Political pressures have increased during the past economic crisis. Actions mainly address treatments for nonlethal indications with large patient numbers, decreasing profit margins. Pharmaceutical companies are continuously trying to come out from this loophole and making strategies against global price cut. In response to this action companies are shifting their business strategies from highly developed **blockbuster model to diversified model**. [(2)]

Due to much patent expiration and rising cost pressure on healthcare, the **generic drug industry** has experienced great growth in the past few years. The global market for generic drugs was worth $107.8 billion USD in 2009 and is projected to reach $129.3 billion USD by 2014 with a CAGR of 9 percent. Generic drugs cost 30 to 80 percent less than their original equivalents this lead **to emergence of Highly Competitive generic Market in Pharmaceutical industry**. This price cut also hurt the generic companies more than originator because their margin are comparatively low than originator. Hence trends of consolidation and specialization can be observed in generic industry. Other considers integration of more value added steps as a mean to increase their profitability.

The global pharmaceutical industry is witnessing a disproportionate scenario in recent years where there is large number of patent expiries coupled with lower introduction of innovative drugs. This is leading to global pharmaceutical companies strategically **outsourcing** their manufacturing and research jobs to countries like India, china while increasing their focus on introducing low cost generic drugs. Outsourcing activities can be in multiple segments right from the drug discovery till manufacturing of the final products.

Several large, high-profile pharmaceutical companies have recently sought to improve their Competitive posture and overall company performance by **developing promising product lines** through **licensing, engaging in joint ventures, divesting (or "spinning off") unprofitable business segments, and negotiating mergers and acquisitions (M&As). M&As,** which result in industry consolidation, arguably have the most significant effect on the pharmaceutical industry as a whole..

The dynamic and high-potential pharmerging markets offer tremendous opportunities for drug manufacturers. Big Pharma's drive into a group of high-potential "pharmerging" markets has continued to gather momentum. Emerging market offer attractive opportunity for growth it is important to prioritize entry into them. China as emerge as tier 1 market, attracting significant foreign capital. India, Brazil, Russian and Venezuela are next in the line and offer substantial growth opportunity. M&A has emerged as the preferred model for entry into emerging markets, but with there being relatively few attractive targets; companies are compelled to pay high valuations. Over a period of time**, collaboration may be viewed as a more viable option for companies.**

According to MC Kinsey Report –India pharma 2015:unlocking the potential of Indian pharmaceutical market, multinational company have been vying for a piece of this pies for some time now, but India represents ,myriad of challenges and it differ greatly from developed market. Apart from this, India has highest number of USFDA compliant manufacturing units (outside the US) to produce huge quantities of bulk drugs and formulation products complying stringent quality norms for global pharmaceutical companies, thus Indian companies have huge opportunity to export their quality driven low cast generic product.[3]

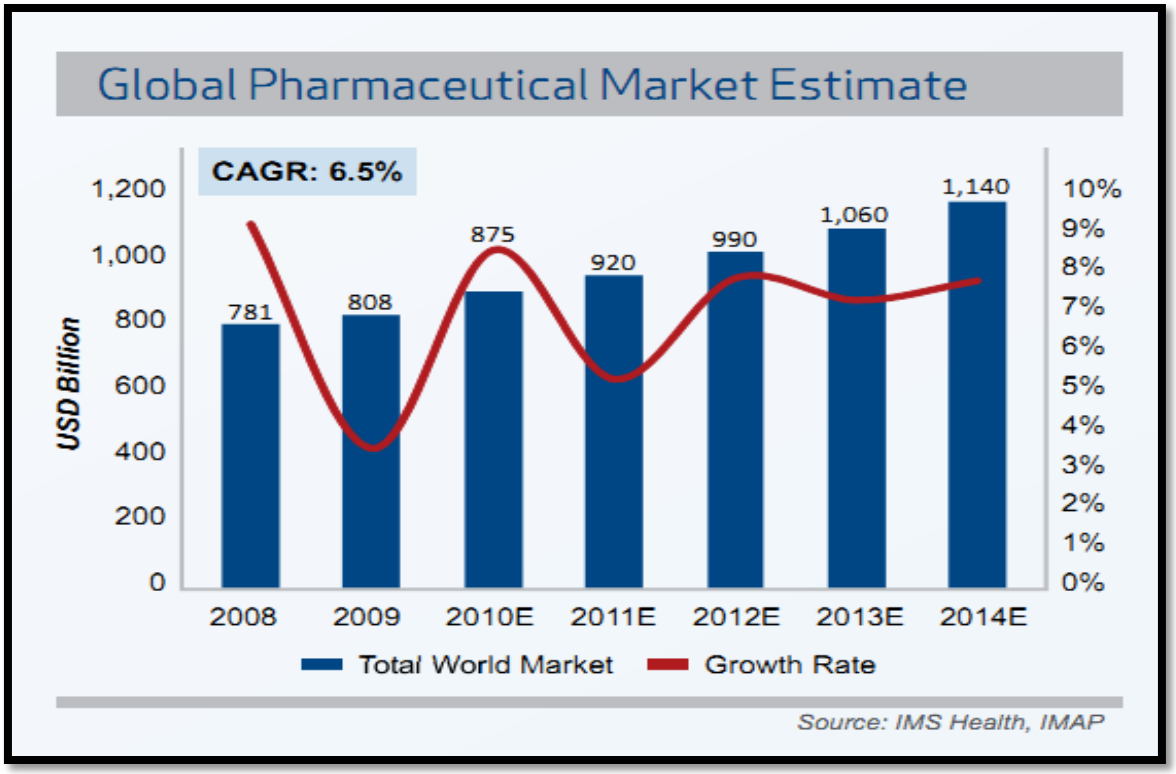
Table No.1: List of Pharmerging Country

List of Pharmerging Countries

Tiers	Countries	2009 GDP based on PPP valuation (Trillion USD)	Incremental Pharma Market Growth from 2009-13 (Billion USD)
Tier 1	1: China	9	40B+
Tier 2	2: Brazil 3: Russia 4: India	2-4	5-15B
Tier 3	5: Venezuela 6: Poland 7: Argentina 8: Turkey 9: Mexico 10: Vietnam 11: S. Africa 12: Thailand 13: Indonesia 14: Romania 15: Egypt 16: Pakistan 17: Ukraine	<2	1-5B

Source: IMS Health, IMAP

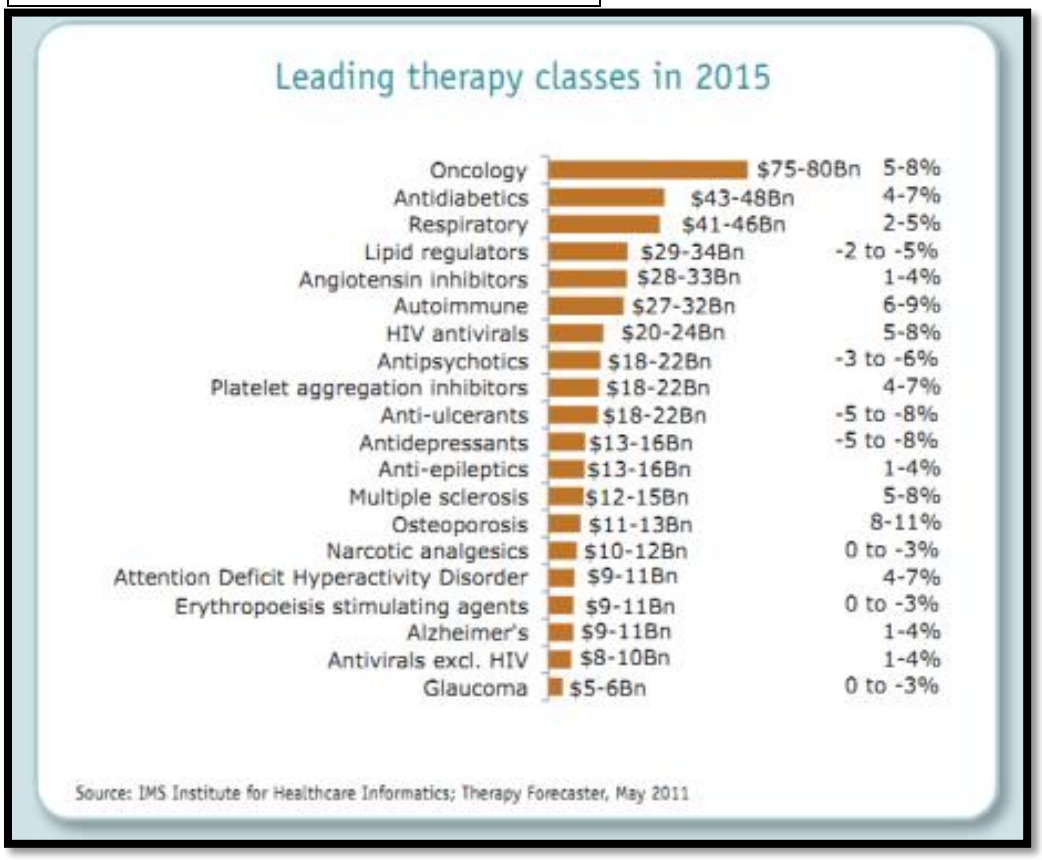
Figure No.1: Global Pharmaceutical Market Estimate



6. KEY FACTS AND FIGURE [1, 2, 3, 4]

1. Global pharmaceutical market is expected to grow with 8.6% and reached at level of $990 billion USD by 2012.
2. Generic industry is projected to reach at $129.3 billion USD by 2014 with CAGR of 9.5%.
3. Global pharma market is expected to expand $1.1 trillion USD by 2014.
4. During the next five-year period (2010- 2014), the revenues of drugs having patents that will expire are about $89.5 billion USD.
5. Cancer has rising therapeutic and commercial importance, as more than 20 million new cases of cancer are predicted in 2025, compared with 12 million in 2008. Moreover, approximately 25 to 30 new anti-cancer agents are expected to be approved for a variety of new indications, helping to expand the treated patient population. Global sales of cancer drugs will grow at a CAGR of 12 to 15 percent, reaching $75-80 billion USD by 2012.

Figure No.2: Leading Therapy Classes In 2015



6. Through 2015, biologic drugs worth more than $80 billion USD in global sales will lose patent protection, presenting a major opportunity.

7. Spending on medicines will reach nearly $1,100Bn in 2015, reflecting a slowing growth rate of 3-6% over the five year period compared to 6.2% annual growth over the past five years.

8. The global pharmaceutical industry which was earlier product-centric now has diversified product and market portfolio.

9. McKinsey & Company's report, "India Pharma 2020: Propelling access and acceptance, realizing true potential," predicted that the Indian pharmaceuticals market will grow to US$55 billion in 2020; and if aggressive growth strategies are implemented, it has further potential to reach US$70 billion by 2020.

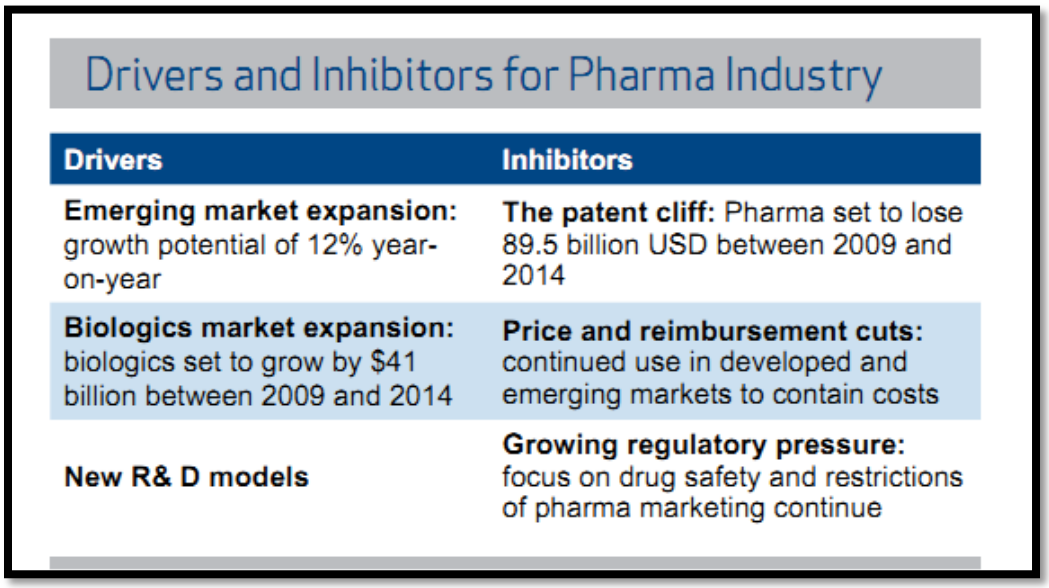
10. The global pharma market is in its transformation phase, with its focus changing from a blockbuster to a healthy outcome-based approach.
11. The growth of these markets is expected to lead to a new world order in the pharma industry. Global Over the counter (OTC) market is expected to revenue of $78.5bn by 2015.(kaloroma)
12. China has emerged as the leading emerging market, with Brazil, India and Russia featuring in the next tier of emerging markets.

7. KEY CHALLENGES

The main challenges for drug companies come from four areas. First, they must deal with **competition** from within and without the industry. Second, they must manage within a **world of price controls** that dictate a wide range of prices from place to place. Third, companies must be constantly on **guard for patent violations** and seek legal protection in new and growing global markets. Finally, they must manage their product pipelines so that patent expirations do not leave them without protection for their investment. Other challenges are -

- Governments challenging and imposing price controls wherever Possible.
- Major regulatory authorities undergoing change following a great deal of adverse publicity and skepticism.
- The difficulty and ever-rising expense of developing new small Molecules and converting them into potential blockbusters.
- The clock marching ever forward toward patent expiry, with no Imminent drug replacements in sight. Also Patent cliff and its impact on pharma industry.
- Challenge abounds in OTC business in Pharma Industry.
- Big Pharma R&D pipeline are Drying Up.
- Legal and Infrastructure Hurdle in emerging market.

Figure No.3: Drivers and Inhibitors for Pharma Industry



8. PRICE CUT AND ITS IMPACT ON PHARMA INDUSTRY [5]

Pharmaceutical companies have to operate in a highly regulated environment; the degree of regulation to a significant extent depends on the country and type of the product. One of the most important aspects of government regulation for pharmaceutical companies is price regulation, and different countries have different policies on this issue.

The majority of European countries control drug prices, and this downward pressure on prices has been increasing during last year. Japan has even stricter price controls than European countries; all prices are controlled by the government, and they are subject to a periodic price review. As the result of price control, prices of the same products can significantly differ in different countries.

Both generic and MNCs are under pressure to maintain their profit margin and finding the way to fight against price cut. MNCs are greatly affected by price cut in industry; they are finding difficulty to access the market and their market share are continuously decreasing due to high prices. MNCs are trying to enter in the emerging market either by tie up with generic companies or by M&As. Another thing that is threatening to MNCs is the pressure by government to issue compulsory licensing. Generic companies are also facing prominent challenges from government intervention on pricing issue in pharma industry. Although their profit margins are very low and there business is characterized by volume driven low price business they are finding difficult to survive in competitive environment. Companies are either merging or finding innovative cost effective way to produce the drug products. This price cut in industry lead to decline in Profit before tax by one fifth for domestic companies.

8.1 Overview of price cut in world

China: - In efforts to contain the growth in healthcare expenditure in China National Development and Reform Commission (NDRC), continuously lowering the MRP of drugs. The primary objective of this price cut is to bring down the price of drug with high average daily cost and to narrow the gap between off-patent originator drugs of MNCs and local products. So far, NDRC has launched 28 round of price cut since 1998.

India :- The Government of India, through a draft National Pharma Pricing Policy (NPPP) aims to control prices of 348 drugs based on the National List of Essential Medicines recently prepared by the Health Ministry of India (60% of drugs marketed in the country).

The draft policy seeks to regulate prices of drug formulations only, unlike the existing principle of controlling prices of specified bulk drugs and their formulations as adopted in the existing drug policy, 1994.

The key changes from the existing policy are namely:

1. The adoption of market based pricing (MBP) for fixing formulation prices instead of cost based pricing (CBP) followed currently;

2. The current ceiling limit of 10 % on the yearly permissible hike of prices of non-scheduled drugs may be revised to 15 %.

3. Control of formulations prices only.

Japan: -The ethical drug prices in Japan are regulated under the National Health Insurance System. The National Health Insurance (NHI) reviews the prices of drugs every two years. Recently the NHI has revised prices downwards. They find it important to consider the balance of cost and benefit, and the pharmacoeconomic evaluation when the NHI price is revised.

Korea: - The South Korean government has announced a drastic 'One-Shot Drug Price Cut' policy for country. The reason why it is called "drastic" is in respect to its timing. To date the pricing of generic drugs have gradually fallen since the expiry of the patent for the original drug until the price reached approx. 70-80% of the original drug price. However according to the 'One-Shot Drug Price Cut' policy, generic prices will be cut to 53% of the original price. During the first year of the patent expiration, the original price of the branded drug will also be reduced to 70% (30% cut) and the generic price will be reduced to 59% (41% cut) of the original price and then to 53% (47% cut) in year 2.

The policy applies to about 7,500 drugs, he Government is also hoping that this will result in domestic companies finally changing their strategy towards R&D development, no t solely sales oriented.

Taiwan: - Drug price cuts by Taiwan's Bureau of National Health Insurance (BNHI) have aroused strong opposition from the pharmaceutical industry. BHNI announced series of biennial price reductions that have proven extremely disruptive to Taiwan's pharma industry. The return on investment for drug companies has been steadily declining due to BHNI's previous six rounds of price cuts over the past decade.

Canada: - Patented medicine price review board is charged with review of price of patented medicine and responsible for remedying excessive pricing. Administered board calculate a maximum average factory gate price that a manufacturer can charge for patented medicine regardless of whether generic alternatives are available .if manufacturer average price id above this price, board may allege excessive pricing and a hearing may be commenced.

Spain: - uses of price cuts and reference group to reduce the drug's bill.

United Kingdom: - Continuous use of risk sharing scheme (effective drug discounting) for expensive drugs.

Brazil: - Cost containment pressure may result in cuts in the drugs' budget.

With the global price cut pharmaceutical companies are continuously making strategy to survive in taught situation. Small Cap companies will consider business restructuring; starting new complimentary businesses or potentially in more severe cases withdrawing completely. Mid cap companies are divided into two groups; one having much more resources to resist this turbulence whilst the other group not having the ability to withstand these changes alone. The former will most likely buy the latter so as to expand their capacity to increase the number and volume products being manufactured locally. For the large cap companies, there could also be strategic M&A opportunities among them to make up their weakened market position.

9. STRATEGIES ADOPTED BY PHARMA COMPANIES AGAINST PRICE CUT [2]

Pharma companies face a number of resistors to profit growth including the looming patent cliff, pricing pressure by government also by competitors causing a significant slowing in branded sales, coupled with ongoing R&D challenges. Hence companies are therefore taking to boosting performance through enhancing operating profit through a Combination of operating margin and sales growth. The global pharma market is in a state of transformation with its focus changing from a blockbuster drug to a healthy outcome based approach**.** The industry is responding to challenge of patent cliff, decreasing R&D productivity, pricing pressure, globalization and changing demographics with implementation of new strategic initiatives-

Market: Penetrating emerging markets and their growing middle class to drive future growth.

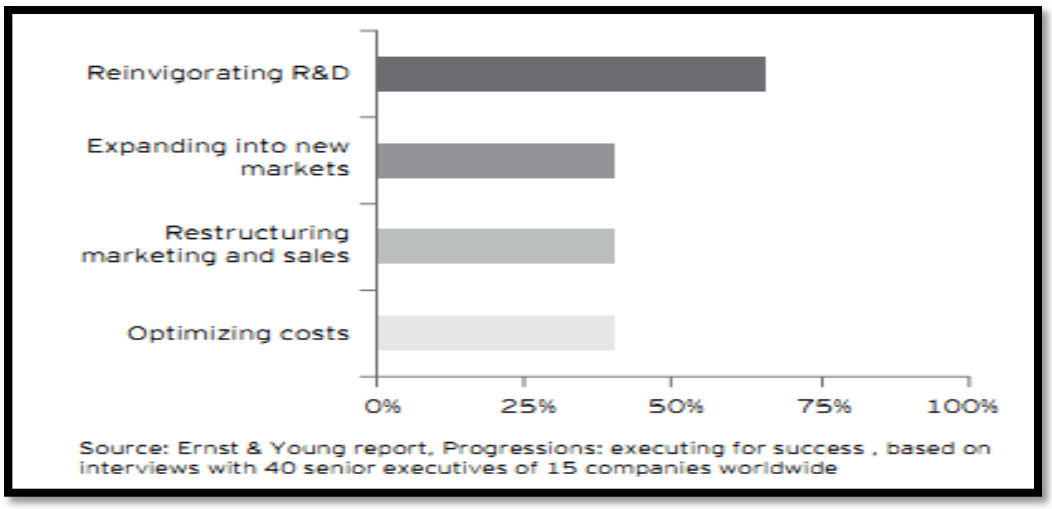
Science: Invigorating pipelines, breaking down silos, collaborating with biotech companies and licensing in late stage molecules.

Customer: Moving from a product to a customer-centric approach.

In response to the current challenges of industry, **pharma companies** are ensuring growth via three key strategies: **innovation, diversification, and cost cutting**.

These strategic responses are achieved primarily through restructuring, collaborative and licensing deals, and M&A.

Figure No.4: Key initiative of Global Pharma Companies



9.1 STRATEGIES ADOPTED BY PHARMA COMPANIES AGAINST GOVERNMENT PRICE CUT

9.1.1 Changing product portfolio

9.1.2 Diversification of business

9.1.3 Merger and Acquisition

9.1.4 Reinvigorating R&D

9.1.5 Export and Outsourcing

9.1.6 Collaboration or Strategic Partnership

9.1.7 Cost cutting strategies

9.2 STRATEGIES ADOPTED BY PHARMA COMPANIES AGAINST TRADE PRICE CUT

9.2.1 Co marketing and Co manufacturing.

9.2.2 Access to new market and Selecting Target segment (SBU development)

9.2.3 Cost cutting and decrease Profit margin and balance it by high volume sale.

9.2.4 Innovate the product and also give more value to product.

9.2.5 Heavy sale Promotion ultimately creating Strong Brand image.

9.1.1 Changing Product Portfolio [1, 2]

Pharmaceutical companies are undergoing major changes to cope with the new challenges of the modern economy. The globalization of the business, the diversity and complexity of new drugs, the increasing tightness of capita, price cut and the diminishing protection provided by patents are some of the factors driving these changes. All stages of the business value chain are suffering the impact: from the development of new drugs to the management of the manufacturing and marketing networks.

Many companies have altered their drug portfolio from primary care **driven blockbusters towards specialties such as Oncology, Diabetes, immunology and inflammation and cholesterol reducing drugs**, where medical need is so high that prices are more easily accepted by regulators.

Global Healthcare industry is being reshaped by dramatic shift away from acute care towards the chronic care. Pharmaceutical companies shifting their focus from market share capture to market creation, also shifting towards super core model. This Model involving the search for, and distribution of a small number of drugs from Chronic Therapy Area that achieve substantial global sales. **The success of this model depends on achieving large returns from a small number of drugs in order to pay for the high cost of the drug discovery and development process for a large number of patients.** Total revenues are highly dependent on sales from a small number of drugs.

Figure No.5

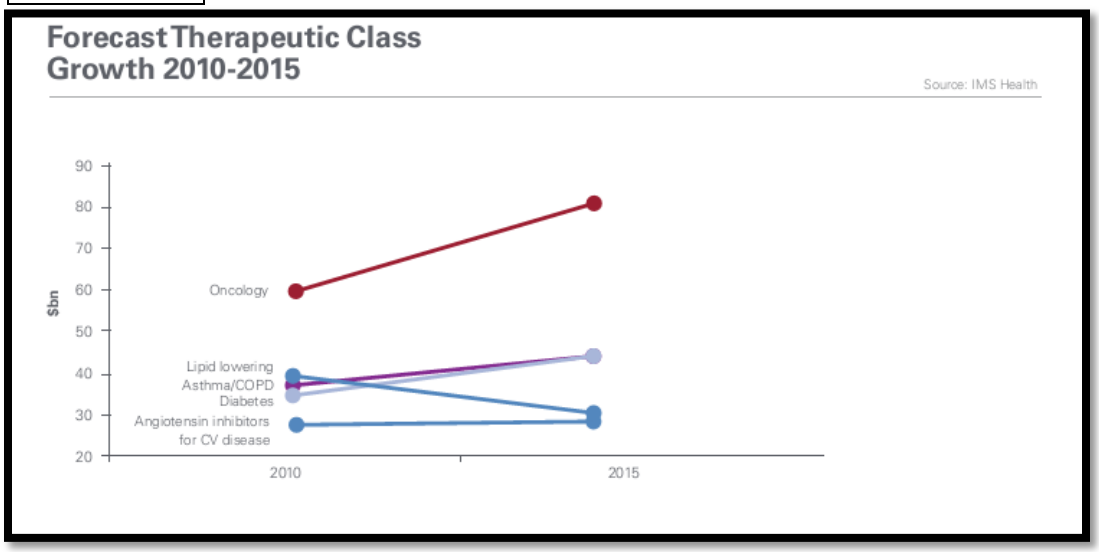
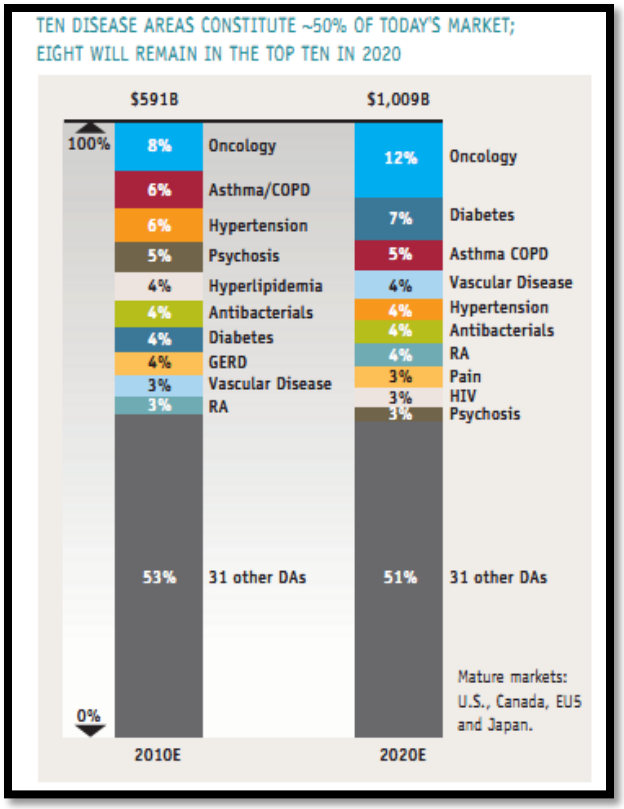


Figure No. 6: Top 10 disease Market share by sale



9.1.2 Diversification of business [2]

The Patent cliff, decreasing R&D productivity, pricing pressure, globalization and changing demographic trends that have been compelling pharmaceutical companies to reinvent their business model. Pharmaceutical companies now have diversified products and market portfolio as compared to a blockbuster based one.

In order to gain operating income, companies are diversified their product portfolio into following segments

a. OTC market development
b. Nutritional and diet Supplement market
c. Biotechnological and Biosimilar product development
d. API and Bulk Drug Industry

Figure No.7

List of Players by Strategy

Diversification* Strategy Followers	Focus Pharma Players
Abbott	Amgen
Bayer	Astra Zeneca
GSK	Eli Lilly
Johnson & Johnson	Pfizer
Merck Schering Plough	
Novartis	
Roche	
Sanofi-Aventis	

** Apart from core pharma services Includes in OTC, vaccine, branded generics, eye care, medical devices, generics etc.*

Source: IMAP

OTC market development :

OTC Drugs' are drugs sold legally 'Over the Counter', i.e. without any prescription of a registered medical practitioner. Those drugs that are not included in the list of prescription and are considered as non-prescription drugs or OTC drugs. Prescription drugs fall under two schedules of the Drug and Cosmetics Rules, 1945: Schedule H and Schedule X. Drugs falling under Schedule G require the following mandatory text on the label: Caution: It is dangerous to take this preparation except under medical supervision. These drugs are not advertised to the public voluntarily by the industry.

But OTC Drugs can be given without the doctor's prescription.

OTC market is segmented into-

1. Vitamins, Minerals & Supplements
2. Cough, Cold & Allergy
3. Gastrointestinal
4. Analgesics
5. Dermatological

With the increase in pressure on pharma companies due to decrease in their profit Margin, Pharmaceutical companies trying to switching their product from Rx to OTC segment. Also MNCs are ready to pay huge money to buy the OTC segments of domestic companies**. Recently U.S- based Abbott has acquired Piramal Healthcare Solutions business (Domestic Formulations) for an up-front payment of USD 2.12 billion and an additional USD 400 million annually for the next four years.** Piramal Healthcare, has strong growth in anti-infective, dermatology, nutritionals and OTC segment, had launched 32 new products and has been ranked no. 1 in the Indian Pharmaceutical Industry in terms of sales from new products. Piramal also has approximated of Rs 1.9bn sale from OTC segment. This are all acquired by US giant Abbott.

Future Growth:

Demographic trends, lifestyles changes, clinical advances and Global pharma industry challenge like price cut, patent cliff are transforming medicine and creating Opportunities for therapeutic areas and drug types in OTC pharma. Consumers are increasingly willing to self-medicate, for convenience and cost savings in particular. New regulations are changing OTC retail channels and sales processes, including the range of products on offer. Importantly,

governments and healthcare providers are promoting self-medication, viewing the process as a tool to help contain healthcare expenditure. Therefore the OTC pharma market holds high potential for continued growth in both mature and emerging geographical markets. According to kaloroma data global OTC market is estimated to grow to Rs. 78 billion by 2012 with a CAGR 3%.

Figure No.8: Life Cycle of Pharmaceutical Product with and without a switch to OTC status

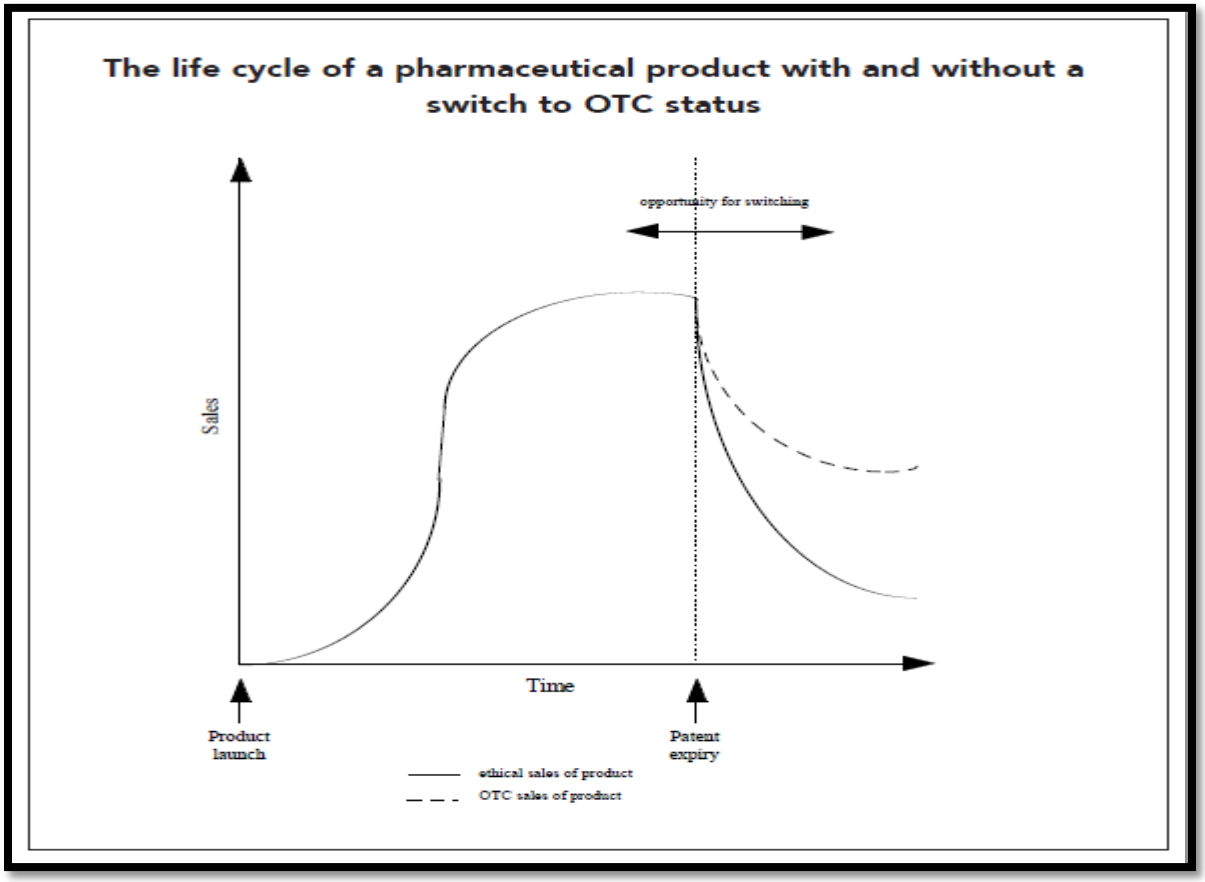
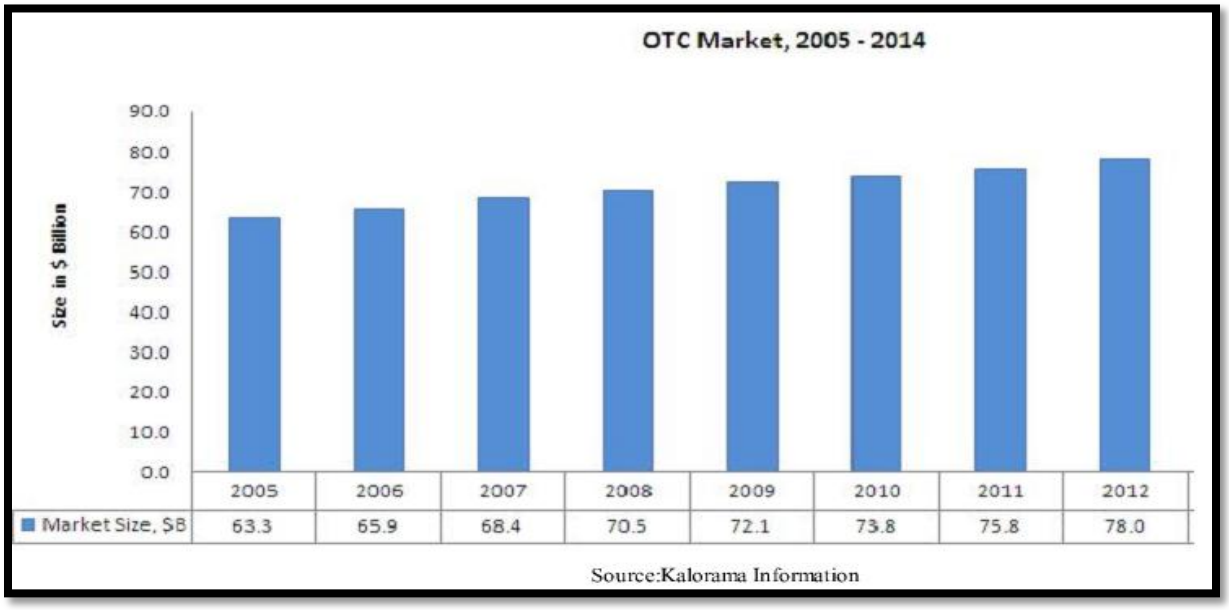


Figure No.8: OTC Market Growth 2005-14



Nutraceutical and Diet supplement market:

Nutraceuticals have emerged as one of the brightest spots in a global market suffering from its worst economic crisis, as several first timers turned towards healthy food to reduce their medical bills. Initial apprehensions regarding the recession making huge dents into the Nutraceuticals industry proved false as customers traded down from their regular diet towards Nutraceuticals to boost their immune systems to restrict medical expenditure. Though the overall Nutraceuticals market has been able to stave off any major recessional effect, the growth rate slightly tapered down as not all segments could cope with the recession in similar manner. Majority of the Nutraceuticals that experienced a squeeze in sales during 2008 and 2009 were priced on the higher side. Among the segments, functional foods witnessed impressive growth as they provide cheaper alternatives to medical bills in the long run. On the other hand, sales for premium products such as organic and healthy food declined, as people traded down to more affordable nutrition.

The Dietary supplements segment represents a relatively mature market, particularly in the developed markets. The herbal supplements sub-segment witnessed slow down in recent years owing to negative media environment, especially concerning drug interactions. Functional foods that constitute the faster growing segment in the Nutraceuticals market, is rising in popularity, as the segment offers a cheaper alternative to supplements.

Growth in the segment is more profound in categories such as cholesterol lowering dairy foods and digestive health products.

"World Nutraceutical Ingredients to 2015," a report from The Fredonia Group, Cleveland OH, expects world demand for Nutraceutical ingredients to increase 7.2% annually to $23.7 billion in 2015, driven by substances with clinically confirmed health benefits and broad applications in foods, beverages, dietary supplements and adult and pediatric nutritional preparations all providing the best growth opportunities.

Pharmaceutical companies are moving their product portfolio towards Nutraceutical market because there is no price cut in Nutraceutical and diet supplements, also some drivers for growing Nutraceutical industry are :-

1. Increasing Consumer Health awareness
2. Increase in disposable income
3. Increased Co Prescription with regular drugs
4. Increase in Life style diseases

As per Indian scenario, NPPA has the authority to monitor and fix the prices of drugs; it cannot take any action if the same drug is re-launched as a food supplement.

Drug companies such as Ranbaxy, Merck, Trikko and Indochem, Pirmal, (Supracive) Dabur (Nutrigo) etc., all have transferred some of the products from the medicine category to the dietary supplement category. They received manufacturing licenses under the Prevention of Food Adulteration Act. Several examples of brands include Evion 400, Revital, Recharge Plus and Sort Z Gold, which were all initially marketed as drugs but later became food supplements. Companies prefer to sell products as food supplements due to the fact that food supplements do not have price controls.

Biotechnological and biosimilar product development:-

The lure of biosimilar, decreasing drug price and stringent regulatory matter in pharma industry is also enticing companies outside the pharmaceutical arena to develop biosimilar capabilities—**an interest that emphasizes the potential size of the biosimilar market.** Drug makers are seeking biotechnology acquisitions to bolster their product pipelines as

biologics become a hot area of research and profitability. For biosimilar (equivalents of off-patent biotech drugs), the regulatory demands are much higher, requiring full-blown phase I and III studies for each production line, as small changes in manufacturing can substantially impact the medical outcome. However, successful biosimilar commercialization will be a marathon, not a sprint, and prospective market players must commit to the long term when they enter the biosimilar arena.

Through 2015, biologic drugs worth more than $80 billion USD in global sales will lose patent protection, presenting a major opportunity[2]. Given this potential, Big Pharma companies are poised to enter the biosimilar market. Even the larger generics players are in danger of being overtaken by the originator drug companies, with Merck & Co., AstraZeneca and Eli Lilly all looking to carve out a share for themselves in the biosimilar market. By acquiring Ranbaxy, Daiichi-Sankyo has gained a certain degree of biosimilar know-how, through the Ranbaxy's association with Indian biotech company Zenotech. Ranbaxy entered into collaboration with Zenotech over a period of two years prior to acquiring a stake in the company in 2007. Zenotech has three biosimilar on the Indian market with a pipeline reportedly representing a third of the $65 billion USD global biologics market. Another interesting development is the joint venture between Teva and contract manufacturing giant Lonza. This gives Teva access to the most important assets in the biosimilar game, production expertise and capacity.

Future Growth:-

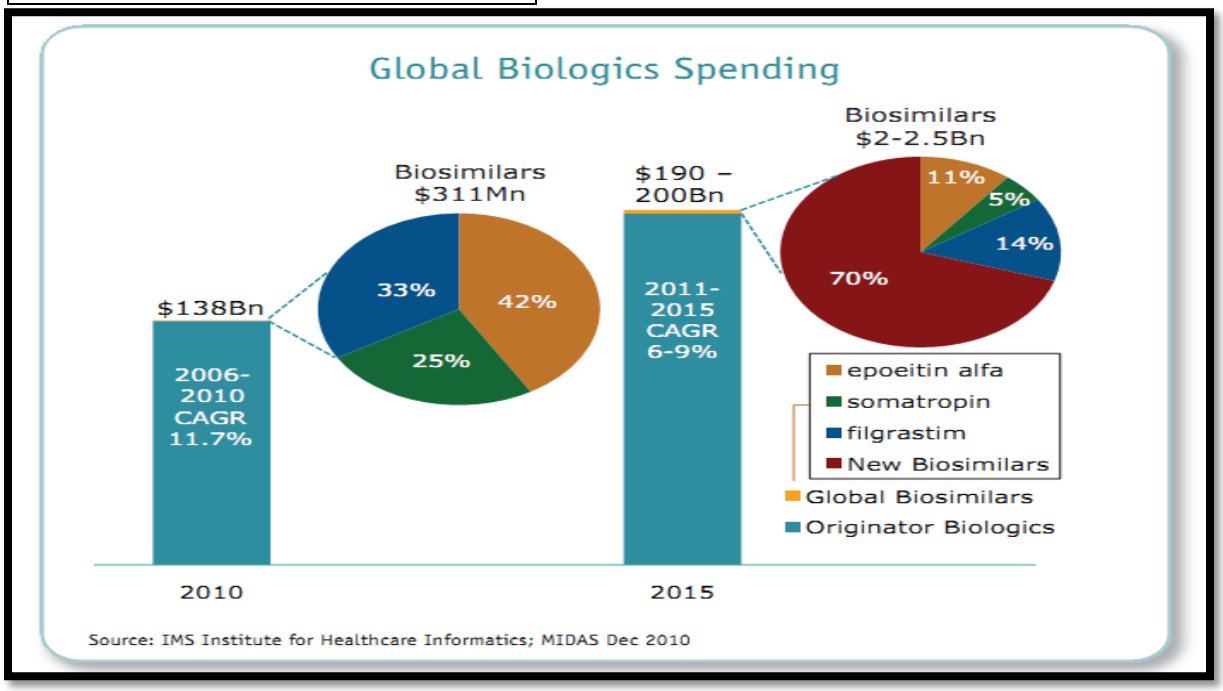
GIA announces the release of a comprehensive global report on Biosimilars markets. The global market for biosimilars is forecast to reach US$17.9 billion by the year 2017. The market is driven primarily by the increasing demand for biotech drugs, cost-effectiveness of biosimilars in comparison to their expensive counterparts, impending patent expiries of major biotechnology drugs, aging population and increasing incidence of cancer and other critical diseases.

EU has taken the lead on the biosimilar front. It has also become the testing ground for biosimilar drugs, with three biosimilar having entered the market — hGH, EPO and filgrastim. All three were first launched in Germany, the largest generics market in Europe, with one of the highest levels of uptake. The generic-friendly nature of the German market, driven by strong payer pressure, makes a favorable scenario for the biosimilar segment.

Indeed, the German biosimilar market will contribute to almost half of all seven major markets overtaken by the US biosimilar market.

The US market represents the greatest opportunity for the Emerging biosimilar industry, and is forecast to constitute nearly 90 percent of the seven major market biosimilar volume markets in 2014. The size of the US market, combined with typically high generic substitution that characterizes it, makes it an attractive prospect for potential biosimilar players.

Figure No.10: Global Biologics Spending



API and Bulk drug Market:-

The Active Pharmaceutical Ingredient (API) forms the most vital part of every formulated end product, and is an important part of the whole pharmaceutical industry. The overall API market was valued at $101.08 billion in 2010, and is expected to grow at a CAGR of 7.9% from 2011 to 2016.

The Development in the High Potency Active Pharmaceutical Ingredient (HPAPI) and Biogeneric drugs is boosting the growth of the Active Pharmaceutical Ingredient (API) market. There has been a paradigm shift in the use of innovative drugs to that of low-cost API drugs after the economic recession, thereby causing a positive impact on the overall growth of the API market. In order to keep abreast with this change, API manufacturers are applying various novel technologies to reduce the processing time and reducing cost in order to yield more production. In order to reduce the total overall manufacturing cost pharmaceutical companies becoming self sufficient in API and Bulk drug supply and fining cost effective way to produce this APIs.

The API market is facing a period of unprecedented growth as market dynamics have undergone a major change with the expiration of patents pertaining to global blockbuster drugs in the U.S. The consequences of the economic crisis has hit the Innovative drugs market hard, with less budgets allocated by the major players for the R&D of Innovative drugs. This has led to drying up of pipelines for new drugs, and therefore the market for generic drugs is quickly growing. Thus, the patent expiry factor is slated to drive the API market for the coming years. The API outsourcing trend within the global pharmaceutical industry remains intact as pharmaceutical companies are increasingly looking to maintain focus on core competencies, access new technologies, preserve capital and ensure multiple sources of raw material supply. However, API suppliers in Europe and US are facing increasing pricing pressures due to presence of low cost providers in developing markets, excess big pharma capacity, and backward integration by certain generic companies. Recently a news from the economics times shows that Indian pharmaceutical companies are filling DMF for raw material supply to US companies. About 51% of total Global application for DMF are filled by Indian pharmaceutical companies to supply the bulk drug in US market.

Also as per the new policy of NPPA, Bulk drugs are exempted from the price control only formulations are considered for price cut lead to have greater growth opportunities for domestic bulk drug manufacturers in India. This decision in India as exempt bulk drug from NPPA will encourage investment in local production of bulk drug and thereby reduce reliance on import. Thus The domestic bulk drug industry is poised to benefit from the impending patent expiries in the regulated markets (including many blockbuster drugs) leading to increase in generic penetration; thereby providing a significant opportunity for supply of APIs to manufacturers of such generic drugs coupled with increased outsourcing of bulk drugs by multinational pharmaceutical companies.

Mergers and collaborations are the strategies that have been noticed across the API industry. Newer market entrants are causing threats to the existing small and medium manufactures, leading to high competition. To overcome these challenges, companies are now forming joint ventures for sharing the technology to manufacture API drugs. The key to survive in the market for SMEs is joint ventures.

Other than this the HPAPI (High Potent Active pharmaceutical ingredient) market is driving the API market growth globally at a fast rate. As these compounds are extremely effective in the treatment of cancers, respiratory disorders, and hormonal imbalances, the HPAPIs market is mostly driven by the growth in the oncology therapeutics market worldwide. The global HPAPI market is valued at $8,900 million in 2011, growing at a CAGR of 8.3% till 2016.

The HPAPI compounds are highly effective due to the targeted therapy. Hence, its application for cancers is a major driver. The market of North America is the largest and accounts for major share; followed by Europe; but Asia is growing at a higher CAGR as compared to North America & Europe. The major players for the HPAPI market are SAFC, Novasep, Lonza, Boehringer Ingelheim, and Carbogen Amics.

9.1.3 Reinvigorating the R&D [6]

With industry consolidation, the economic downturn, pricing pressure and an increasing threat from generics, pharma companies are coming under greater pressure to fill their pipelines with innovative cost effective drugs. However, despite the costs and risks involved

in drug development, the pharma industry is finding new ways to streamline the R&D process in an effort to increase efficiency and output.

As R&D pipeline are drying out, many companies have started to experiment with new R&D models. For example, **GlaxoSmithKline has restructured its R&D centers to emulate biotech R&D culture**. The company hopes to replicate an entrepreneurial culture in a large pharma organization**. Eli Lilly acquired ImClone to source innovation from outside the company and then left it as a stand-alone unit operating independently, much as Roche did extremely successfully with Genentech. Pfizer and GSK broke down corporate barriers to share intellectual property and assets to develop new drugs for diseases such as HIV**. Several pharma companies are partnering with leading academic institutions to promote innovation from basic research.

Now days there are few issues which are not yet solved by government regarding the patent of product, that's why companies are focusing on R&D in biotechnology and developing biosimilars. It would be restructuring R&D, with an aim on improving focus and reallocating resources to key pipeline assets and activities. R&D is the engine that powers a pharmaceutical company. It is also a high-risk endeavor. Furthermore, given all of the hurdles that now exist especially with regard to ensuring safety and having sufficient novelty to justify pricing, R&D is more expensive than ever. But, for blockbuster drug, companies have to invest – substantially.

Apart from this Governments are encouraging to develop strong R&Ds like they are providing loan facility for R&D. that's why New Pricing Policy exempted the patented drug from price cut. After heavy investment in R&D companies can have space to talk to government about the price cut.

Broadly, to raise innovation returns back to the level that prevailed in the era of blockbusters, pharma companies need transformational change. Pressing areas of improvement for pharma companies are: increasing managerial autonomy; aligning research goals with incentives; attracting and retaining the right, creative talent; minimizing bureaucracy; and creating flexible organizations.

R&D in pharmaceutical industry can be reinvigorating by following options:-

Scientific and clinical leadership development that builds a highly effective cohort of discovery and development "managers in the middle" who have extensive external networks, broad disease and pathway understanding, and decision-making authority given established scientific and clinical targets, coupled with performance measures that encourage collaboration and overall portfolio optimization.

Disciplined portfolio management based on assessments against rigorous, forward-looking target product profiles that have been externally tested against market and competitive trends.

Targeted therapy development involving systematic and early identification of targeted therapy options, analysis of trade-offs, and selective design of tailored drug development programs to focus on patient subpopulations, including co development of diagnostics as appropriate.

Scale-up of next-generation clinical development that focuses on rapid and broad rollout of new approaches such as building access to high-quality electronic medical record data for protocol modeling and patient recruitment, remote data collection, and novel approaches to data quality risk monitoring, as well as aligning the design of outsourcing partnerships with strategic development goals.

Apart from this if the industry is to become more innovative and cut its R&D costs, four features will be vital:

1. A comprehensive understanding of how the human body works at the molecular level:-
At present, when pharmaceutical companies start investigating biological targets, they may know relatively little about how those targets are involved in the diseases they want to treat. The information they possess usually comes from academic literature and patents, and is often based on animal studies, which may not be relevant to the way in which a disease progresses in humans. It is generally only in Phase II clinical trials that companies test whether modulating a particular target with a particular molecule is efficacious in treating a disease in man. So companies have to understand the proper physiology of body and made the artificial target element as **virtual vermin** that might reduce the duration and cost of R&D. The American Diabetes Association and US biopharmaceutical company Entelos have developed a diabetic virtual mouse that is being used to Study cures for Type 1 diabetes.

Figure No.11a: Current Research Process

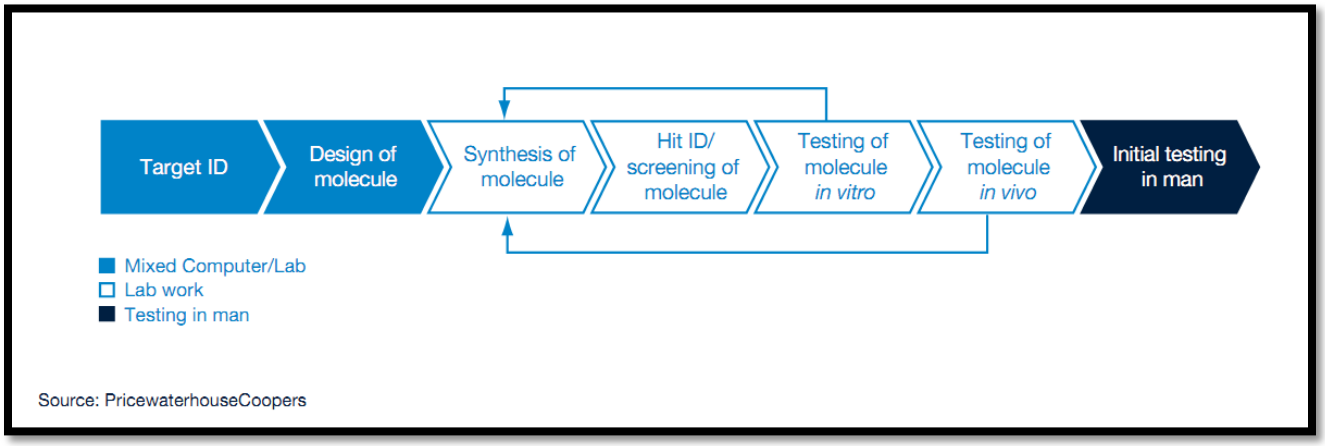
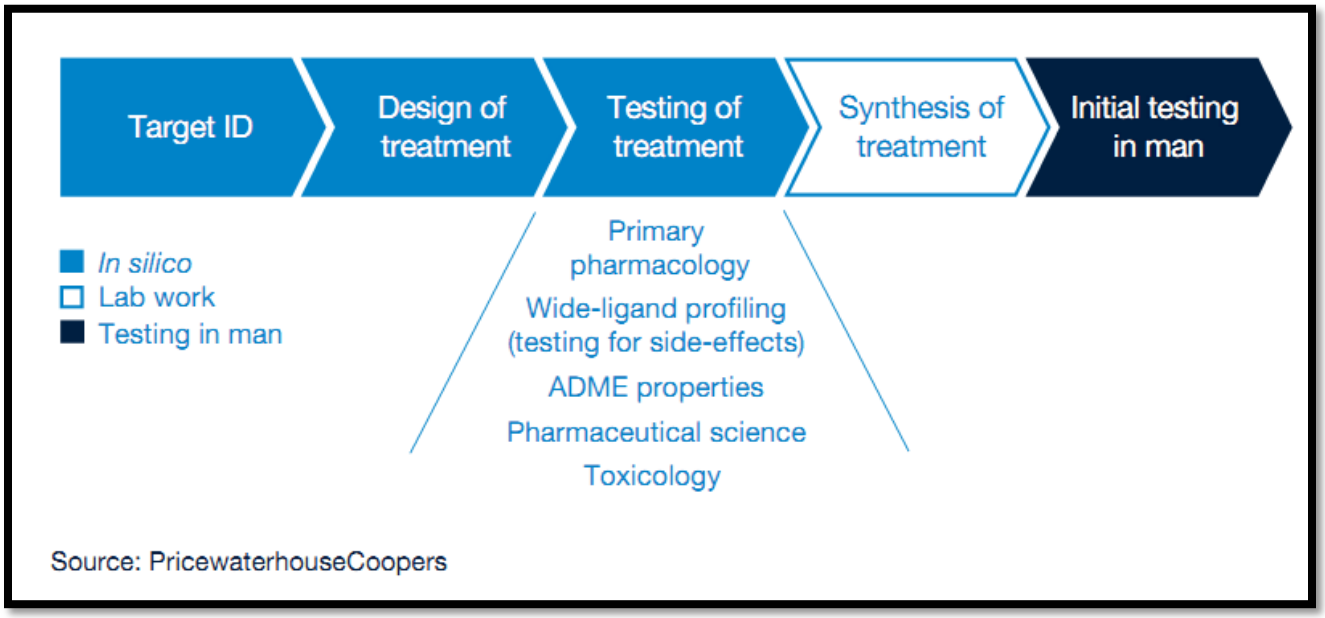


Figure No.11b: Research Process might look like when virtual man exist



In silico methods are currently used to design new molecules, where the structure of the target is known and the interactions between the target and virtual molecules can be modeled. But researchers more commonly use in vitro screens to find molecules that "hit" a designated target, and further screens to test the physical and toxicological properties of these molecules.

2. A much better grasp of the path physiology of disease (by which we mean the functional changes associated with, or arising from, disease or injury)

3. Greater use of new technologies to "virtualise" the research process and accelerate clinical development;

4. Greater collaboration between the industry, academia, the regulators, governments and healthcare providers.

9.1.4 Export and outsourcing

Outsourcing and exporting the economical drugs become the Pharmaceutical Industry's Strategy of Choice for Managing Risk and Rapid Change. Due to much patent expiration, the generic drug industry has experienced great growth in the past few years. The global Market for generic drugs was worth $107.8 billion USD in 2009 and is projected to reach $129.3 billion USD by 2014 with a CAGR of 9 percent. Rising cost pressure on healthcare has resulted in an increase in generic pharmaceutical usage —generic drugs cost 30 to 80 percent less than their original equivalents. Generic Companies from Emerging market is planning to manufacture drug product via reverse engineering process **and exporting** this drug to Tier 1 market like US because during last five year (2010-2014) the revenues of drugs having **patents that will expire are about $89.5 billion USD,** that have a great opportunity for the generic companies to export their drugs. India have highest no. of FDA approved plant outside the US, so it would be great opportunity for Indian company to export their product to US and other tier 1 market.

Soaring drug discovery development times, prolonged regulation-mandated testing and review processes, rapidly escalating R&D expenditures and competition are hurting the margins of pharma companies. This is driving them to **outsource** various services to cheaper destinations, including India. This trend is now moving from generics and contract manufacturing to research. Market forces and governmental initiatives have placed downward pressure on pharmaceutical and biotechnology companies' drug prices. Pharmaceutical industry is responding to these pressures by converting some of the fixed costs of maintaining research and development personnel and facilities to variable costs, which can be increased or decreased as needed, by outsourcing drug development activities to contract research organizations. In addition to Outsourcing only in R&D field, Pharmaceutical companies are likely to outsource a wide range of manufacturing-related activities, including: primary and secondary packaging; formulation; active ingredient

manufacturing; labeling; clinical supplies; sterilization manufacturing of chemical intermediates; and stability packaging. By working with a wide range of outsourcing partners rather than investing in new plants, equipment and personnel, pharmaceutical manufacturers can cope with uncertainty and exploit emerging opportunities as a result of new partnerships.

In addition to this, Pharmaceutical companies are continuously filling dossier for active pharmaceutical ingredients (APIs). DMFs are essentially approvals to supply complex raw materials to all generic manufacturers servicing in the US market, which is the most lucrative of all global markets.

Outsourcing allow the companies to pursue potential new revenue streams outside of their core focused area, and to benefit from improved productivity, emerging technology, in licensing opportunity and increased growth. Outsourcing has also become a strategy of choice for moving multiple projects forward simultaneously Thus, Outsourcing provides a mechanism for leveraging risk, plus the flexibility to adapt to rapidly changing conditions.

9.1.5 Cost cutting Strategy [7]

The pharmaceutical industry, including drug companies and contract manufacturers, is under pressure to bring down costs, particularly in manufacturing, R&D and other Invariable costs, due to an increased focus on emerging markets."Genericization" of pharmaceutical products and indirect consequences of the global economic downturn, Companies are introducing "green" technologies and processes, and expanding the outsourcing of production, as part of the cost-cutting effort. Developed as well as emerging markets are going through a genericization phase, in which pricing plays a vital role because generics are a low-priced but volume-driven Business.

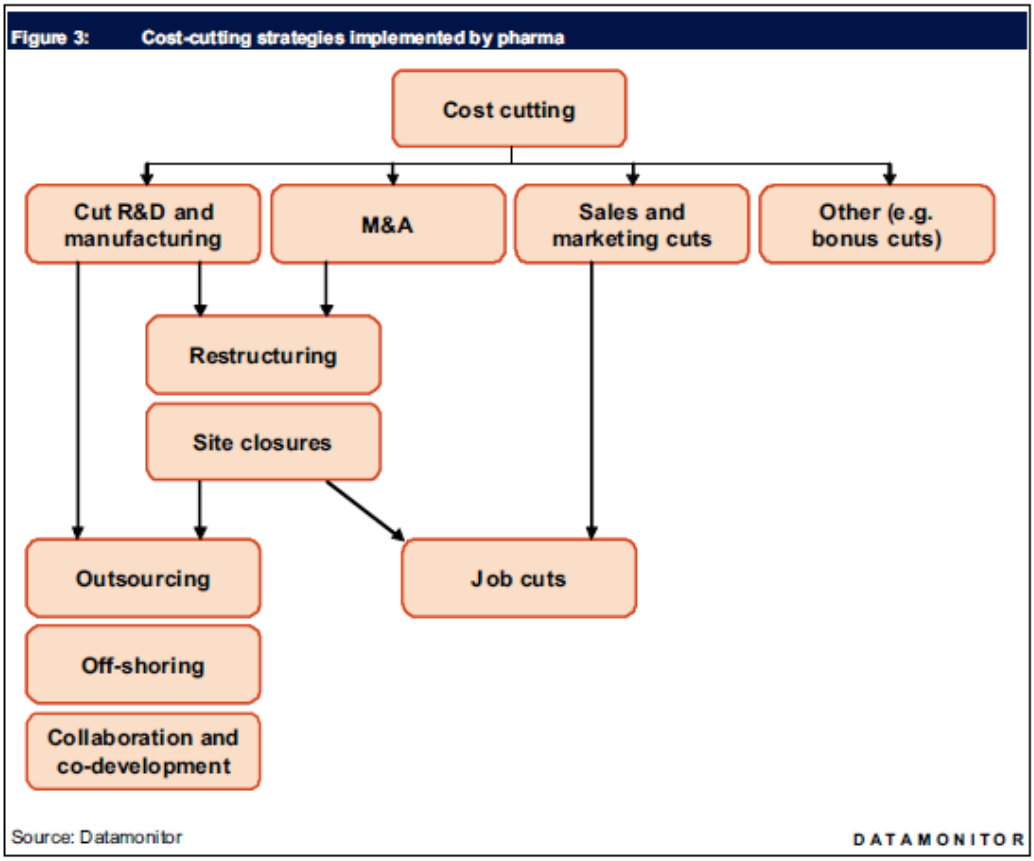
Green Technology refers that pharmaceutical companies are using strategies such as solvent reduction and replacement, refining a chemical route, and biocatalysts to optimize certain API syntheses while achieving improved environmental profiles.

Pharmaceutical companies around the world are pressured to lower costs, not only due to the current global economic slowdown, but also due to continuing pricing pressure, the pro-generic agenda, and the drying research and development pipe-line.

The use of better manufacturing processes, including green technology, is also helping pharma companies and contract manufacturers to cut costs and stay competitive. Pfizer says that multiple initiatives involving operational excellence and lean manufacturing, as well as several green programs across the company's manufacturing and supply network, is paying off. MNCs are constantly looking for ways to manage processes more efficiently and effectively. **Lean manufacturing, process analytical technology, and green chemistry have all yielded, and continue to yield, cost savings.** Green chemistry tool box" includes route scouting with enzymes and the use of micro-reactor technologies for commercial-scale production. The tool box involves chemo catalysis and biocatalysts, process intensification, and the proactive management of learning curves to increase yield and reduce waste.

Cost cutting will be required to grow profitability in the face of slowing sales growth. Mega-mergers have been used as a pivotal tool for cutting costs and growing sales, ultimately bolstering operating profit.

Cost Cutting Strategy in Pharma Industry:-



Other than this suggested cost cutting Methods are -

Reshape cost management: Traditional cost management approaches aren't cutting it in today's hypercompetitive marketplace. To create the leaner, more agile cost structure required to survive in the future, companies need to carefully evaluate proven strategies that are shown to drive sustainable cost management.

Make fixed costs more variable: This concept acknowledges that there is a lot of variability within the individual components that contribute to a company's overall performance but that many companies aren't able to effectively flex or modulate their spending accordingly.

Manage costs through collaboration: There are many aspects of the pharmaceutical value chain that require companies to engage in expensive, resource-intensive services that don't fundamentally offer competitive advantage and differential returns. Managing costs through

collaboration focuses on creating collaborative models with industry partners in selected areas to tap the required capabilities

9.1.6 Collaboration and Strategic Alliances [(2)]

A strategic alliance is "an agreement between firms to do business together in way to that go beyond the normal company-to-company dealing, but fall short of merger or full partnership". This alliance ranges from informal "handshake" agreement to formal agreement with lengthy contract in which parties may also exchange equity, or contribute capital to form a joint venture corporation. These cooperative arrangements seek to achieve organizational objectives better through collaboration than through competition**.** Strategic alliance helping the SMEs to survive in such competitive and price cut environment in following ways:-

1. Critical to the success of a core business goal or objective: -

Cost reduction may also be a core business objective of the alliance, particularly among supply-side partners. By investing together in new processes, technologies and standards, alliance partners can obtain substantial **cost savings** in their internal operations. Again, however, a cost-saving alliance is not truly strategic unless it has an underlying business objective, such as "to achieve an industry-leading cost structure.

2. **Critical to the development or maintenance of a core competency or other source of competitive advantage: -**

Learning alliances are the most common form of Competitive/competency strategic alliance. If any pharmaceutical company need to build incremental skills in an area of importance is often accelerated with the help of an experienced partner.

3. Blocks a competitive threat: -

It is strategic to bring competitive parity to a secondary segment of the market in which the firm competes, when the absence of parity creates a competitive disadvantage in the related primary segments of that market. For example, competing in the high and medium price range of a market with a premium product may leave the firm vulnerable to a low price entry. If the firm's manufacturing processes do not permit the creation of a low-priced product

entry, a strategic alliance with a volume partner in an adjacent market can successfully Block the competitive threat.

4. Creates or maintains strategic choices for the firm: -

From a longer-term perspective, an alliance that is not fundamental to achieving a business objective today could become critical in the future. Small sized companies can strengthen their distribution to the other countries of world with alliance with local companies.

5. Mitigates a significant risk to the business: -

When an alliance is driven by intent to mitigate significant risk to an underlying business objective, the nature of the risk and its potential impact on the underlying business objective are the key determinants of whether or not it is truly strategic.

Few examples of Strategic Alliances in Pharma Industry:

In — licensing products:

MNCs have typically in-licensed their products for two reasons.

1. Despite their significant interest in emerging market, many companies had a product portfolio that was more aligned to western markets. In order to operate in emerging markets, they have in-licensed products from companies, especially in countries such as India, to augment their portfolios.

2. in addition because of increase in genericization due to patent expiry and austerity measure adopted by the government in their own country, they have in licensed product even for the US and European market.

Table No.2: Licensing deals

Licensing deals

Year	Deal partners	Therapeutic areas	Geographic focus
2011	Bausch & Lomb – Micro Laboratories	Eye care	India
2011	Nycomed –Roche	Bonviva (treatment of osteoporosis)	China, Hong Kong, Malaysia, Australia, New Zealand, the Philippines, Singapore, Taiwan and Vietnam
2011	sanofi-aventis – Glenmark	Crohn's disease, multiple sclerosis	North America, Europe, Japan, Argentina, China , Uruguay, Brazil, Russia and India
2010	Abbott – Zydus Cadila	Pain, cancer, cardiovascular, neurological and respiratory	Fifteen high-growth emerging markets
2010	AstraZeneca – Torrent Pharma	18 generic products	Nine emerging markets

Sources: Press releases, news reports

R&D and co-development:-

Companies have further entered into R&D and co-development deals to develop drugs targeted at the emerging markets. Such deals would drive synergies through the branded generics R&D capabilities of the local companies and the clinical, registration and geographical footprint of the Big Pharma.

Table No. 3: R&D and Co- development

R&D and co-development

Year	Deal partners	Therapeutic areas	Geographic focus
2011	Bausch & Lomb – Micro Laboratories	Eye care	Emerging markets
2010	Merck – Sun Pharma	Developing, manufacturing and commercializing branded generics	Emerging markets
2009	Eli lilly – Zydus Cadila	Cardiovascular	-
2009	GSK – DRL	Cardiovascular, diabetes, oncology, gastroenterology and pain management	Emerging markets including Africa, the Middle East, Latin America and the Asia Pacific, excluding India
2008	J&J – Advinus	Metabolic, inflammatory and neglected diseases	-

Sources: Press releases, news reports

Co-marketing:-

The success of product's introduction depends on its ability to reach out to a large segment of doctors. Since several MNC pharma companies tend to have small sales teams and

Are focused on a few geographies, they have been forging.co-marketing agreements to help them increase their product reach in the market and thereby the sale probability of these products. China has seen a relatively large number of deals in the marketing and distribution segments. Around 38% of all deals in China are co-marketing and distribution transactions.

Table No. 4: Co marketing deal

Co-marketing deals

Year	Deal partners	Therapeutic areas	Geographic focus
2011	Bayer – Zydus Cadila	Women's health, diagnostic imaging, cardiovascular diseases, diabetic treatment and oncology	India
2010	Merck – Sinopharm	HPV and other vaccines	China
2010	MSD – Adcock –Ingram	OTC and selected prescriptions	South Africa
2010	GSK-Dong A pharma	Proprietary, generics and biologics	South Korea
2009	GSK – Amgen	Post-menopausal osteoporosis	Emerging markets including China, Brazil, India and South Korea

Sources: Press releases, news reports

Pharma Biotech strategic alliances:-

A partnership between a pharma and a biotech or another pharma is formed to co develop a compound. Pharma companies and biotech bring complementary strengths to their strategic alliances. Typically, biotech is set up to pursue programs with a high degree of risk, or less validity in terms of proof of concept. They can bring innovative approaches to diseases and conditions and, ultimately, offer pharma the opportunity to add to its pipeline. Pharma companies typically form strategic alliances with biotech when there is some validation of the biotechs' programs in their areas of interest. The pharma companies bring much-needed resources as well as expertise to a partnership. Example the collaboration between Human Genome Sciences (HGSI) and GlaxoSmithKline continues to bring a new lupus-treating drug to market.

Examples of strategic alliances by Indian companies:-

After Ranbaxy's acquisition in 2008, at least eight Indian companies have entered into tie-ups with MNCs. Almost all known names in India's pharma sector – Dr Reddy's, Sun Pharma, Aurobindo Pharma, Torrent Pharma, Lupin, Natco Pharma, Emcure Laboratories and Claris Lifesciences - have some form of agreement to either manufacture, market or supply drugs to India and other countries.

Natco, which has a tie-up with US' third-largest generic manufacturer Mylan for licence and supply generic version of Teva's patented 'Copaxone', a drug prescribed for multiple sclerosis, says that for Indian companies, this means assured business and profits. "It could, therefore, be a win-win situation for both the partners.

Sandoz entered into a strategic alliance with Nipro Corporation, which will focus on a broad range of cross-licensing and co-development opportunities for the Japanese generics market. The specific areas of cooperation will include both cross-licensing of existing product portfolios, as well as co-development of future pipeline products across a number of therapeutic areas. The companies have already identified complementary opportunities that capitalize on their individual strengths, including Sandoz's global leadership in anti-infective and expertise in oncology injectables, and Nipro's modern technologies.

9.1.7 Merger and acquisition [2]

M&A offer the opportunity **to grow scale and cut costs** through elimination of duplicate operations, **Access to innovative pipeline products and externalization enables low-risk**. Ultimately, such strategies can be used to increase profitability, although M&A at least in the long term is not a sustainable strategy. Other than this M&A is considered as tool for gaining the market share by horizontally merging with competitive company, also to gain a competitive advantage within the marketplace.

Now days Pharma companies are turning to M&A to consolidate their core businesses, and to get access to new areas of Growth. Global pharma players continue to penetrate the burgeoning emerging markets by acquisition of domestic generics and manufacturing companies.

MNCs and Domestic companies have different purpose for doing merger and acquisition. Due to expiration of patent, stringent regulatory pressure and price cut by the government, forcing MNCs to acquire domestic companies of emerging market also to **expand and diversification of their product portfolio so that revenue loss** due to expiration of patent can be compensated. Pharmaceutical Companies have been increasingly using acquisitions as a strategy to increase their presence in emerging Markets.

Domestic companies finding it difficult to survive in the huge competitive environment because they have low price but volume driven business so they are merging with small domestic companies and with the local player of other country so that they can expand their volume driven business in other country also.

Table No. 5: Example of M&A

Example of Merger and Acquisition:

Year	Bidder-Target	Deal value	Rational
2011	J&J-JB Chem	US $ 0.26 bn	1. JB Chems business - More than 50% of its revenue coming from Russia and CIS country
			2. Strong OTC brand In Russia
2011	Takeda-Nycomed	US $ 14 bn	1. Nycomed- 39% of its Revenue comes from emerging market
			Nycomed strength in COPD
2011	Amgen- bergamo	US $ 0.215 bn	1. Bergamo's Strong possession in brazil hospital supply and oncology Medicine
2010	Reckitt-benckiser paras	US $ 0.724 bn	1. Firm foothold in OTC Pharma Market with Paras Brand
			2. Material healthcare synergy in India
2010	Sanofi aventis-BMP sunstone	US $ 0.52 bn	1. BMP sunsone's Stong Platform in Cough and cold and Women's health segment in China
			2. Enhanced Presence in Consumer Healthcare Market
2010	Abbott-Piramal	US $ 3.72 bn	1. Expansion into Indian market by leveraging Piramal's 300 branded generic medicine
2009	Abbott-Solavy	US $ 6.20 bn	1. Solvay - 75% of revenue other than US
			2. Around 70% of Revenue from Branded generic
			3. Expansion into emerging market in

			eastern Europe and Asia
2008	Daiichi-Ranbaxy	US $ 5.48 bn	1. Access to Indian market
			2. Leveraging Ranbaxy's generic portfolio for Japanese Market
Source Merger Market Press release, News report			

China has witnessed the maximum number of acquisitions, some supernormal valuations have been for Companies that were based out of India, e.g., Abbott's acquisition of Piramal at 8.7 times the latter's revenues, Reckitt's acquisition of Paras at 8.1 times the latter's revenues and Daiichi's acquisition of Ranbaxy at 4.9 times the latter's revenues. This high valuation can be attributed to the limited availability of attractive assets in these countries.

Incentives for Mergers and Acquisitions by Indian companies

- Build critical mass in terms of marketing, manufacturing and research infrastructure.
- Establish front end presence.
- Diversification into new areas: Tap other geographies / therapeutic segments / customers to enhance product life cycle and build synergies for new products.
- Enhance product, technology and intellectual property portfolio.
- Catapulting market share.

9.2 STRATEGIES AGAINST TRADE PRICE CUT

Due to political pressure on government regarding to reducing the healthcare expenditure, Government continuously reducing the drug price. This lead to increase in competition in pharma industry, mainly among the generic companies. To get the profit within this competitive environment, Generic companies are making strategy to get the market share. Currently following practices are done by pharmaceutical industry to gain the market share.

9.2.1 Access to new market and selecting target segment

Pharmaceutical Companies are also facing a changing environment of increasing health care reforms, technological advances and a customer focused approach. With the increase in expenditure by public on healthcare, government are under pressure and are reducing the price of drugs, this decision causing the cut-throat competition in pharma industry. Generic companies are becoming more vibrant for their economical product promotion. This lead to a consequences that current role of the pharmaceutical industry's sales and marketing workforce will be replaced by a new model as the industry shifts from a mass-market to a target-market approach to increase revenue.

Healthcare marketers are accustomed to dealing with segmented target markets. A target market can be defined as a region, disease state, patient, physician, hospital, insurance provider, age group, sex etc. There is no shortage of audiences for healthcare marketers; Companies are shifting a new marketing and sales system with smaller, more agile and smarter sales force.

Pharmaceutical companies are seeking for the chronic drug market, that is the market where healthcare need s very high also Particular target market segment like baby care products, nutritional products, antibiotics, OTC market, anti infective etc. so that here they can do their volume driven business through monopolized strategy.

Recently Nestle have deal with Pfizer to buy the infant nutrition business of Pfizer, this way nestle want to monopolize in infant nutrition segment.

Also Abbott after acquiring the Piramal healthcare strategized that Abbott might became the leader in OTC segment and here they have strong diversified product portfolio.

The playing field for the pharma industry seems to be changing from **urban to rural markets,** as they feel that the former would be the revenue generator and the latter would spearhead volume growth. Thus pharmaceutical companies are selecting rural area as their target market, because government has already setup essential infrastructure to facilitate healthcare needs and income of rural population increasing day by day. Companies feeling that they can generate greater revenue from that segment.

To hit this opportunity, Lupin has built a strong national sales and distribution network with a special focus on tier II cities, town and villages. Additionally, they have forged strong relationships with local retailers and associations to strengthen their presence across the spectrum, lupin made a very strong below the line programme reaching out directly to doctors—specifically in rural areas—aiming to educate them on best practices, technological developments, benefits and new age treatments.

Another case in point is Piramal Healthcare which has focused on general practitioners, to cater to rural markets to increase its penetration with a field-force of 800 people.

Himalaya has launched a strategic business unit called "Zera" which will focus exclusively on expansion into class 2^{nd} 3^{rd} and 4^{th} town and other rural area. With the introduction of Zera, the Company will increase its total reach to more than two lakh doctors. The promotional Reach would be spread across different specialties, taking the company closer to their objective of achieving one product of Himalaya in each household in the country.

MNCs are also entering into the rural market as novo nordisk is that 'The Changing Diabetes Barometer project' in Goa last year under the banner of Global Changing Diabetes Leadership forum in association with the Goa Government. Through this project the company aims to undertake a massive diabetes control programme, which includes creating mass awareness of diabetes, conducting diabetes screening programmes, enabling practical training camps for medical professionals, improving treatment of diabetes with focus on reducing complications related to diabetes and working towards making Goa free from diabetes related amputation, blindness, nephropathy and other complications. In another

initiative, the company conducts training for anganwadi workers. This education programme covers various aspects of diabetes including early symptoms of diabetes, diagnosis complications and unlearning myths about diabetes. Anganwadi workers are trained health workers in various aspects of preventive health, nutrition and child development covering rural areas. Through this programme, 74 anganwadi workers responsible for maintaining health records of 1,000 to 1,500 people in their area were trained.

The latest entrant to target this market is Elder Pharmaceuticals. Elder, through its Elvista division aims to expand its reach to match the geographic length and breadth of country by investing $8.21 million investment for a rural thrust. Hence, "Elder's strategies are aimed at moving towards tier II to IV towns, villages, talukas to compete with Elder Brand Power," plans are already made to launch topical pain reliever called Ontac Gel in a small blister sachet pack. Outreach techniques to target rural audience would include Mobile Health Clinics, Continuous Medical Education Programme for healthcare professionals.

Also Diversification of business is another option for pharma companies; they are focusing on the biotech, biosimilar, vaccine, nutritional products, diagnostic and medical devices segments, and where the Government intervention is minimum.

9.2.2 Co marketing and Co development

Pharmaceutical companies from emerging market finding it difficult to survive in such a competitive environment, they are finding the way to reduce their risk and also trying to maximize their profit. For that pharmaceutical companies are selecting the strategic alliance in their development and marketing of their product.

(a) Co development Agreement:-

In a Co-Development Agreement the intellectual property is typically licensed by the licensor to the alliance partner, and as well, the two partners together jointly undertake the further development of the intellectual property. In this way the licensor seeks to continue to add value to the development of the intellectual property, beyond just granting a license. By continuing to add value in this way, the licensor is entitled to greater financial remuneration, than if the licensor had passively granted a license and not contributed further to the development of the intellectual property.

Now days Co development are becoming famous among biotech and pharma companies to reinvigorating R&D. also co development of drug share the Risk and also launching of drug in particular geographical area widen the drug portfolio.

(b) Co-Marketing Agreement:-

In a Co-Marketing Agreement the intellectual property is similarly licensed by the licensor to the alliance partner, but additionally, they partner together to jointly market the pharmaceutical products developed from the intellectual property. Value adding here occurs by the alliance partners together accessing their respective marketing networks and resources to jointly take a pharmaceutical product to market**.**

In other words, Co-marketing simply means joining of two or more companies to provide products to end customer. It could be achieved through various means."Either two companies can join hands to promote a product or one company can specialize in manufacturing while the other can take up marketing of the products on an exclusive basis.

Co-marketing strategy is catching up among the pharma companies. Many Midcap pharma Companies are preparing themselves to enter into Co-marketing arrangement. Co-marketing would help in launch of newer products and widening a company's reach. It has a multiplier affect due to combination of sales teams. Co-marketing ought to be adopted as one of the strategies by mid and domestic pharma companies to face the onslaught from bigger companies and MNCs. Also this collaboration enhances both companies' portfolio of offerings to its customers and creates synergistic effect by delivering high quality services and best value to the industry

Both these strategy help the partner in many ways and this could be helpful to survive in low profit margin business by

1. Maximizing financial returns
2. Prohibitive cost of taking a drug to market requires partnering
3. Development of skills

Thus in short, Co marketing and Co development help the Pharma Company in following way:-

1. Two companies have different but complementary research capabilities, So that together they can further develop intellectual property, which is something that neither could do without the other.

2. One company may have a research capability, but no capability to guide a product through its regulatory and clinical pathway, with the second company having the expertise to guide a product through that pathway.

3. One company may have promotion and marketing capability, but no manufacturing capability.

In each of these examples, the companies consider forming a strategic alliance to combine their different but complementary resources and capabilities to bring a product to market.

9.2.3 Cost cutting, decreasing profit margin and balance it by volume driven business

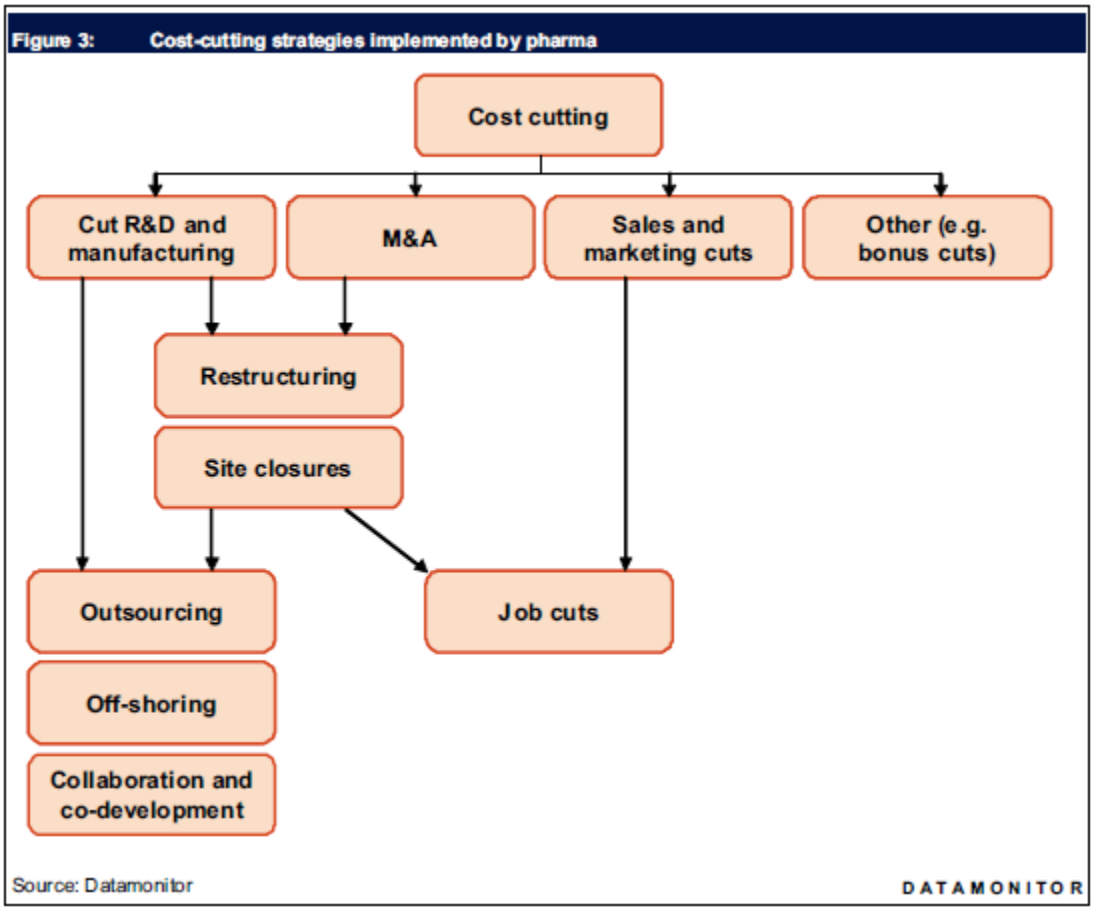
The pressure to control and reduce costs is one of the biggest challenges currently facing the pharmaceutical industry. Successfully stripping out cost from a business is notoriously difficult. In Pharma, the challenge is made even more so because the industry has, until recently, been focused on growth and so there needs to be a cultural change to help companies and employees face the new reality. Such an environment requires an approach that reduces costs in a strategic, disciplined and sustainable manner, delivered at pace.

The pharmaceutical industry, once a thriving sector, has been cutting costs right and left by closing plants, laying off people, outsourcing jobs to third-world countries, and reducing research efforts to the minimum.

Drug discovery jobs have disappeared by the thousands in the pharma industry as the industry has cut costs in order to adjust to what is widely perceived as the end of the blockbuster-drug era. Most of pharma companies are doing retrenchment in order to cut their cost.

Most of MNCs are entering into generic low cost drug production instead of investing into R&D because of market dynamics or in order to do the cost cutting. Generic industry are highly competitive and sensitive in price of drug product so here margin are the less but their believe in volume driven business so that profit margin can be restored.

Cost Cutting Strategy in Pharma Industry



9.2.4 Innovate the Products or add the value to product

Current marketing efforts of pharmaceutical companies are mostly product driven and generally focused. Instead, a differentiated approach to targeted audiences and accounts will be more productive in the long run. Besides, pharmaceutical companies have to develop specific added value to product features to develop new partner relationships with health care professionals.

The concept of value innovation presents to pharmaceutical companies the prospect of an improved market position and performance. It presents:-

A way to develop a unique proposition, and a way to market this proposition to selected parties in the health care market, to develop sustained performance by way of continuing partnership in the business of health on the basis of unique added value to health care professionals and patients.

It is very difficult for domestic and MNCs to make profit in environment where the price is regulated by government. Pharma companies are continuously focusing to bring the innovation in their product to gain the first mover advantage. This is very famous in generic industry where very less profit margin to the companies as compare to patented drug product.

Few example of adding value by way of developing experience co-creation in health care:-

Experience Co-Creation (ECC) is a concept in which the consumer is actively involved in shaping the way in which he or she wants to use offered products and services in specific ways, according to how he or she sees this fit to one's own needs and desires.

Pharmaceutical companies are utilizing following innovation in their product to show better than other's product:

1. Either to implement innovation in packaging like packaging should be more patient compliance as comparative to their competitor.
2. Innovation in marketing strategy like changing the flavor of drug product and make it more patient compliance.
3. Also implementation of innovative strategy in production of drug product like introducing the drug product in different strength.

Innovation in pharma help marketers recover lost ground by exploring new ways to marry traditional strategies with emerging market.

4. Extension of indications of drug product also add the value of drug product, even for MNCs it is better strategy to extend the patented period of drug product.

5. Finding the Novel drug delivery system and make the product more patient compliance.

9.2.5 Heavy sale promotion and building strong brand image [8]

It is said that to get the market share, first have to get the people's mind share for that particular product. Pharmaceutical companies are doing the same for their drug product by investing heavily in promotional activity. The aim of drug promotion is to persuade people to buy more drugs and/or to pay higher prices. This is done by increasing the perceived value of the drug via one or more of several approaches including:

- Increasing the perceived frequency and/or severity of the indications.
- Widening the indications to include more people.
- Increasing the perceived likelihood and magnitude of benefits.
- Decreasing the perceived likelihood and magnitude of harms.
- Increasing the use of drug for longer duration.

Pharmaceutical companies try to identify where people are on the following behavior change stages and then deploy sophisticated marketing techniques to motivate them to move one or more stages towards repeat use:

By investing in sale promotion they want to get the higher market share either by converting brand into OTC or to get the strong Brand equity. Pharmaceutical companies are looking social media as tool for their product promotion. Social media allow the pharmaceutical companies to quick access to their customer and they can innovate their product with their demand.

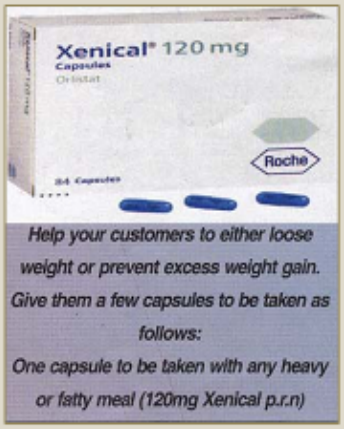
Other than this celebrity endorsement in pharma is becoming famous. Like for Salman khan is promoting Revital of Ranbaxy.

Few strange example of Pharma Promotion:-

- **GSK Ghana 2005 Case**: - Advertisement and public relation technique are the most cost effective way to move the people especially doctors and consumers from unawareness to awareness of existence of new drug and for maintain repeat usage. These techniques are effective mostly by appealing to desire and fear. GSK'S advertisement for Hepatitis B vaccine highlights the fears doctors may face in course of their work, such as premature retirement due to unstable health.

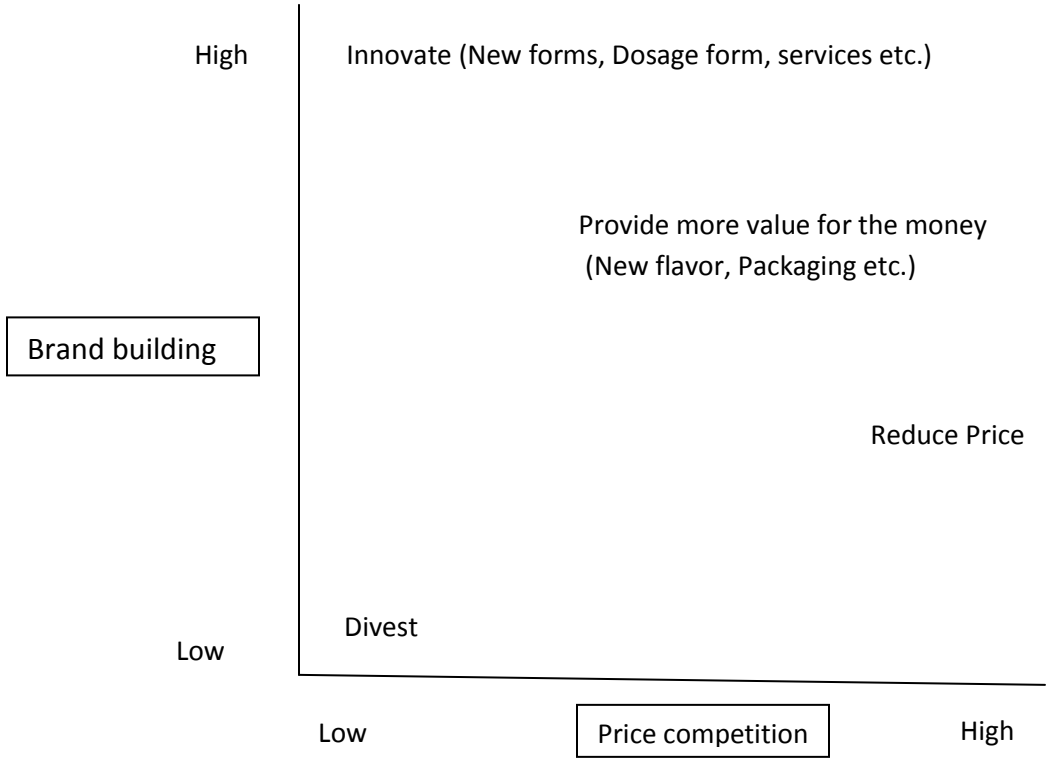
Roche, Ghana, 2003

Pharmaceutical Society of Ghana (PSGH) News. December, 2003



In another example, an article in the Pharmaceutical Society of Ghana's (PSGH) newsletter claimed "Lifestyle modifications [such as diet and exercise] alone are usually ineffective in maintaining weight loss on a long term basis so there is usually the need to institute supported drug therapy." While other types of treatments are mentioned, Roche's Xenical is the only branded product named in the article. Below the packaged Xenical pills, as pictured on the left, the article advised readers to get customers to take one pill after a fatty meal.[54] It is noteworthy that the PSGH'S current disease awareness campaign on Hepatitis B is "ably supported by Roche and GlaxoSmithKline."[55]

Marketing Strategy used by Pharmaceutical Company



Strategies adopted by Pharma companies

Divest:-

This strategy involves cutting all promotional and research expenses once the brand faces direct competition from generics and redirecting the savings towards brands that are still enjoying patent protection. Sometimes, this 'milking' strategy actually involves price increases to take advantage of the higher brand equity of the brand among the smaller segment of hard-core loyal customers. This strategy leads to the lowest levels of brand building (because the brand is not supported) and price competition (because the price advantage of generics is not challenged)

Innovate:-

Short of introducing a completely new molecule, pharmaceutical companies can innovate by launching new forms and dosages or by demonstrating effectiveness for new indications. They can also innovate by offering better services for doctors (eg hotline), and better communication on the illness and on the brand through higher promotion by the medical representatives. Compared with the 'milk and divest' strategy, this option also entails low price competition, but can improve the equity of the off-patent brand by offering additional patent protection.

Provide more value for the money:-

Introducing new and improved flavour, packaging, or delivery systems (eg easy to swallow pills, or patches) can lead to additional emotional or functional consumer benefits (eg higher compliance). The resulting differentiation enhances the awareness and image of the brand and hence increases its equity. Because these innovations typically do not extend patent life however, it is more difficult to pass the costs on to the consumer when facing generic competition and hence, this strategy's lead is one step ahead towards price competition.

11. CONCLUSION

On a more positive note, a scarcity of resources tends to fuel creativity, so, amid this pharma revolution, success will most likely originate from motivated teams who can maximize their proof of concept. Further ahead, innovative approaches, such as patient-driven partnerships and targeted therapies, may result in faster drug development, a greater number of drugs for specific groups and, ultimately, a better outcome for patients. Some also believe that the centre of the pharma industry may move to continents where the production costs are lower, resulting in a loss of global leadership for Europe and the US, but regional success elsewhere. Only time will tell how the pharma story will unfold, in the interim however, it is likely that innovative cost-cutting will remain the industry's mantra.

12. LIMITATION

Data source – The information used in this report is mainly based on Secondary data that are available from internet. Other sources of data are limited.

Access: - Due to lack of resources, can't access the paid sites, books and Report.

Time: - Limited time for summer internship hinders the scope of Report.

13. RECOMMENDATION

1. Cadila pharmaceutical should invest in creating more OTC brands in emerging market because global OTC market is booming in upcoming years.

2. Antineoplastic drug has rising therapeutic and commercial importance, as more than 20 million new cases of cancer are predicted in 2025, compared with 12 million in 2008 that why Company should focus on this category.

3. As Per Marketing strategy adopted by Ranbaxy for their product like revital - to convert it into nutritional product and made it OTC brand to prevent them from price cut, Cadila Should made the same strategy for their product like Vitagrow.

4. Cadila pharmaceutical does not have any product against infertility, due to life style and stress on population infertility rate is increasing so company should plan to have their stand in infertility therapeutic segment.

5. Due to expiration of patent of blockbuster drug in upcoming year, Cadila pharma should merger with local generic company of that particular market and should plan to launch generic version of drug molecule.

6. Cadila pharma should fill the DMF for supply of API to US market because Cadila pharma have US FDA approved plant and US market is demanding cost effective raw material for drug product.

7. Company have strong brand image in rural market via their agro and veterinary product so company should plan to enter into rural market for medicinal product by utilizing target market strategy for rural market.

8. Cadila Pharmaceutical Should think to Co develop Biosimilar molecule with the activity of Strategic alliances and M&A with Multinational Company because biosimilar market is going to be boom in upcoming year.

9. Cadila Pharmaceutical Should outsources the Marketing of new Biosimilar in country like Germany, which contribute almost half of all other biosimilar market.

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