

## Understanding How The Indian Pharmaceutical Industry Works Part 3

### **Key Performance Indicators Pharmaceutical Sector**

#### **Sales & Marketing**

Marketing always starts with the customer and ends with the customer as they are the valuable assets for the country. Marketing is a business activity by which it means that the flow of goods and products will flow from the manufacturer to the customer (End user). Pharmaceutical marketing is a well organized information system. It helps the physicians to update about accessibility safety, effectiveness and techniques of consuming the medicine. The Indian pharmaceutical industry has been gaining momentum in the recent years and is expected to move towards an upward trend. The end users must have awareness about these high technology industries. Complex information must be communicated properly. Proper use of medicines will enable the companies to cut down their costs which in turn help to increase their profits. This post gives an insight about the evolution of Indian pharmaceutical markets, its need and characteristics. It also highlights the present scenario, future prospects, challenges and the strategies to be adopted by the Indian pharmaceutical companies.

#### **Current Scenario Of Indian Pharmaceutical Market**

The Indian Pharmaceutical industry has been witnessing phenomenal growth in recent years, driven by rising consumption levels in the country and strong demand from export markets. The Indian pharmaceutical industry is the most progressive and advanced among all the developed and developing countries. Today, India is among the top five pharmaceutical emerging markets in the world. Demand from the exports market has been growing rapidly due to the capability of Indian players to produce cost-effective drugs with world class manufacturing facilities. Pharmaceutical Marketing helps to raise awareness about treatments for Chronic Diseases, the leading driver of health care spending. India is also expected to become a pharmaceutical research and development (R&D) hub in the next decade with the Department of Pharmaceuticals planning a road map for India to be a global player in the industry by 2020. A recent survey indicates that the Indian Pharmaceutical sector has given employment to approximately 2.86 million people, through 20, 053 units. It is estimated that by the year 2020, India's potential in Research & Development will reach between US\$ 8 billion to US\$ 10 billion. In order to combat the growth slowdown, Pharmaceutical companies need to join hands with Governmental agencies and other stakeholders to redress the challenges and grievances.

## **Research & Development**

The pharmaceutical industry is characterized by heavy R&D expenditure. It is only the large pharmaceutical companies who can allocate significant resources for R&D to introduce new products. As the products are an outcome of significant R&D expenditures incurred by these companies, they have their products patented. The patent allows the companies concerned to wield immense pricing power for their new products. The pharmaceutical industry is one of the most research intensive industries. Pharmaceutical firms invest as much as five times more in research and development, relative to their sales, than the average manufacturing firm. Because increases in spending on drug R&D have been nearly matched by increases in revenue from drug sales, the industry's R&D intensity, the ratio of research and development spending to total sales revenue, has not risen to the extent that R&D expenditures have. Over the past 25 years, R&D intensity has grown by about 50 percent. Most of that growth occurred in the 1980s; since then, the industry's R&D intensity has hovered around 19 percent. A relatively close relationship exists between drug firms' current R&D spending and current sales revenue for two reasons. First, successful new drugs generate large cash flows that can be invested in R&D (their manufacturing costs are usually very low relative to their price). Second, alternative sources of investment capital from the bond and stock markets are not perfect substitutes for cash flow financing. Those alternative sources of capital are more expensive because lenders and prospective new shareholders require compensation (in the form of higher returns) for the additional risk they bear compared with the firm, which has more information about the drug under development, its current status, and its ultimate chance of success. The relative stability of the relationship between pharmaceutical R&D and sales revenue suggests that firms find it most profitable to invest any additional dollar of sales revenue in their own drug research. However, changes in real drug prices can affect companies' R&D intensity or their propensity to invest in R&D from their revenue.

## **ANDA Filings**

A generic company is rewarded for a Para IV filing. The first applicant to submit a substantially completed ANDA (Abbreviated New Drug Application) is given marketing exclusivity for 180 days. Exclusivity means that no company is allowed to launch its product during this period. As a result, there isn't any competition. As the first mover, this helps the manufacturer have an advantage. It can give a boost to market share. This is a valuable opportunity to maximize profit margins without any competition. A branded company can file a case of violation against a generic manufacturer within 45 days of receiving notification from the generic manufacturer. If a case is filed on time, then the stay order for 30 months is given to a brand company. Also, the FDA

suspends the approval of the ANDA for the next 30 months. If the court finds that the patent isn't valid or wouldn't be trespassed, then the FDA can approve the ANDA. Otherwise, it won't be approved.

### **Operating Segment**

It is to be seen that the company basically operates in which segment for e.g : acute or chronic. Reason behind this is that due to present conditions it is observed that people are more reliable on medications. Changes in lifestyle and food habits, aided by higher disposable income, have caused an unprecedented rise in chronic diseases such as cardiovascular (CVS), diabetes, oncology and central nervous system (CNS), according to experts. The middle class has been growing in both the emerging and developed markets. People in these markets have more disposable income and expect better healthcare solutions. Chronic disease cases have risen in number. This has made people become more dependent on medications and health supplements. chronic segments, are increasing rapidly due to the many changes that the country has witnessed over the past few years. These changes could be classified as lifestyle changes, driven by rapid urbanisation, rising incomes of households, westernisation of dietary habits, lack of physical efforts due to improved transportation facilities.

### **Product Pipeline**

A drug pipeline is the set of drug candidates that a pharmaceutical company has under discovery or development at any given point in time. This involves various phases that can broadly be grouped in 4 stages: discovery, pre-clinical, clinical trials and marketing. A Pipeline product is a series of products, either in a state of development, preparation, or production, developed and sold by a company, and ideally in different stages of their life cycle. A product pipeline is an assortment of products and services at various stages of development. At any given time, a company typically has many items in the pipeline. Some of them will make it all the way to production and begin to generate income for the company. One end of the product pipeline is the finished result. At the other end is the brainstorming that leads to a new product. Sometimes company personnel may meet to discuss a new invention, while in other cases, they may engage in discovery activity with the goal of finding potentially new compounds, as seen in the chemical and pharmaceutical industries.

## Patent Filing

Patents are a vital aspect of the global pharma industry. Patent protection is essential to spur basic R&D and make it commercially viable. Patents protect drugs from copycat versions for **20 years** after the drug is invented. This is a bitter pill for pharmaceutical companies because it can take eight years or more after invention to accumulate enough data to get a drug pass the U.S. Food and Drug Administration. Since initial investment in pharmaceutical R&D is costly, strong patent protection is an important step to provide the opportunity to recoup investments in new products. Patents are the legal protection for inventions, including new medicines discovered by research-based pharmaceutical companies. This protection allows a company time to recoup their significant investment in research and development. For a patent to have any commercial value there must be a market for the invention embodied in the patent, which will support the cost of development of the invention and return a profit. In return for such protection, a patent-holder discloses to the world patented research and science underlying the invention. Thus, important scientific information behind a new cancer drug becomes available immediately to researchers worldwide. The market exclusivity and higher prices are made possible by the patent rights function as a reward for the risk undertaken by those who financed the research and development leading to the new technologies.

## Prescription Market

The prescription drug market is divided into two categories:

1. Branded, or patented
2. Generics, or off-patented
  - Branded drugs are patented drugs. When a pharmaceutical company discovers a new drug, it files for a patent. Then, the company is awarded a license for 20 years to exclusively sell the drug. Exclusivity is provided to recoup research and development expenses incurred during the development of a drug.
  - Generics are off-patented drugs. They're bioequivalent—in terms of dosage, form, strength, quality, effect, intended use, side effects, and route of administration—to the branded drugs. A route of administration is a way the medication is introduced to a site in a patient. This could be oral, intravenous, intramuscular, nebulizer, and topical. A few of the leading generic drugs are: Acetaminophen, or Paracetamol, Alprazolam, Amoxicillin, Aspirin, or Acetylsalicylic Acid, Azithromycin, Diclofenac
  - A Drug Generally Has Two Names

- Generic name – a molecular formula
- Brand name – the company's proprietary trademark used for marketing
- Patented drugs are patented by an innovator company.
- Generics are off-patented drugs with a generic name.
- Branded drugs are either patented or generics marketed under a company's specific name. Patented and branded drugs are used interchangeably across the industry.

### **Key Financial Metrics Used In Pharmaceutical Industry**

To understand the pharma business the most important trackable financial metrics are as follow:

#### **Research And Development Expense As A Percent Of Revenue**

Analysing expenses as a percent of revenue is also useful when evaluating pharma companies. Most pharma companies have very high research and development (R&D) budgets because they can only survive and grow by discovering and developing new drugs. Knowing the R&D budget as a percent of revenue helps understand if the company is creating a strong pipeline of future drugs to come on the market. Compare the percent of R&D to revenues to industry standards and also to the company's own spending in past years. Declining R&D ratios can be an indication of a declining pipeline for a company which is a negative signal. R&D as a of revenue in an increasing trend portrays that company has a strong pipeline of drugs which is going to be launched in future and will lead to increase in revenue.

#### **Profit Margin**

Profit margin is another vital metric. Operating profit margin lets the investor understand the impact from R&D to see if the program is bringing successful candidates to the market, whether the marketing and selling costs are having a positive impact on revenues (market share gains), and whether external factors are negatively impacting the company. It is not uncommon for new, novel drugs to have high profit margins, while the overall company margins are much lower.

### **Selling Cost As A Percentage Of Revenue**

Selling cost as a percentage of revenue in an decreasing trend portrays that company is able to sell its product in the market without expensing much on advertisement as well as on selling and distribution cost and that clearly states that demand for that product is prevailing in the market.

### **Employee cost as percentage of revenue**

Employee cost as percentage of revenue says that company is spending more and more revenue on employee expenditure which can be concluded as company is employing more no. of people to meet the future demand and there fore it can be said that company is able to see a good future for the company in coming few years.

### **Dividend to earnings**

Dividend to earnings in a pharma company is an important ratio because as major pharma companies are cash rich companies , investors expects these company to redeploy capital back to shareholders in form of dividends or any other capital structure programme.

## **Porter's Five Force Analysis**

One model for examining an industry and a company's strategic position within its industry is Porter's Five Forces analysis.

### Industry Analysis – Porters 5 Forces Model



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#### **1) Barriers To Entry**

The big payoffs available in the pharmaceutical industry lead to a steady flow of new companies being created. A team of researchers with an innovative idea or newly granted patents can find venture capital funds eager to provide millions of dollars in startup funding. These smaller companies pose no serious threat to big pharma. In fact, one of a startup investor's main exit strategies is to sell out to a big pharma firm when new products are through the initial development phase.

#### **2) Supplier Power**

Suppliers have very little power in the pharmaceutical industry. The raw materials for manufacturing drugs are commodity products in the chemical industry, which are available from numerous sources. Most of the equipment used in manufacturing and research is available from multiple manufacturers. Suppliers usually offer multiple products to the manufacturer, which moderates pricing on rarer materials and unique equipment.

### **3) Buyer Power**

Pharma is unique among industries because the medical patient has an absolute lack of power regarding pricing. The prescriber of the drugs, the physician, ethically is not allowed to profit from the sale of drugs. The entity that pays for the drugs, the insurance company, only has a say in how much it will pay to the distributor of the drugs, meaning it has little power with the drug manufacturers. The insurer can refuse to pay for treatments it believes are overpriced. The only entities with any negotiating power are the pharmacies and medical institutions that fulfill the medical patients' prescriptions. Even these entities have little power over newer drugs under patent or drugs with only one manufacturer. Pharmacies focus on their profit margins and have little incentive to provide patients with the lowest possible pricing.

### **4) Threat Of Substitute And Compliments**

The effect of substitutes is dependent on the individual drug. A new FDA-approved blockbuster drug that has patent protection, treats a major health condition and is first to market in its category has a license to print billions of dollars. The development of a new drug that cures a major disease could be worth tens of billions of dollars per year. Once a drug loses its patents, generic drug manufacturers start selling copycat versions at substantially lower prices. A drug that netted \$100 million a year in profit could become one that earns only \$1 million a year in profit overnight. Additionally, there is a major international problem with counterfeit drugs. The best of these counterfeits duplicates a real drug's formula and sells it at a lower price, which hurts corporate profits. The worst counterfeits are made with low-grade materials and can destroy the reputations of the legitimate products.

### **5) Competition**

With more than \$1 trillion in global sales, pharmaceutical business can be cutthroat. The huge importance of intellectual property results in strong competition for high-level workers and leading researchers. Even strong non-disclosure and non-compete clauses cannot prevent the leaking of competitive information. Any potential new drug has its public information analysed for the possibility of creating a similar drug to market as a substitute. The industry exhibits a pattern of firms merging and larger firms buying smaller firms that have promising research or new drugs.