Potential Risk Factors Influencing The Indian Pharmaceutical Industry - An Exploratory Study

V. Y. John

INTRODUCTION

The Indian Economy has been growing at a phenomenal growth rate of more than 8.5% during the period 2003-08. "Pharmaceutical industry's growth moved in tandem with the economy's growth rate which has been growing at a Compounded Annual Growth Rate of 7.7% during the last five years and during the year 2005, was $5.1 billion in size in comparison with the global pharmaceutical market which stood at $ 550 billion in size"[1].

Companies like Ranbaxy Laboratories, Dr.Reddy's Laboratories, Wockhardt Ltd. are eying for lucrative acquisitions. Leading pharmaceutical companies are pursuing inorganic growth routes and expanding their operations across the world pursuing their goal of aggressive growth and diversification. It is observed that there is an exponential growth in the size of the operations, number of countries to which exports are being made and different segments of products catering to diseases like AIDS, cardiovascular, gastro enteric, carcinogenic and lifestyle diseases. The industry is facing many severe challenges, opportunities and constraints from the government, market forces in the national and international markets, customers, regulatory bodies and its operations within.Many issues like cost overruns, quality assurance systems, low margins, researching, developing and launching new products, phasing out unviable products, diversifying into new lines of business and the like keep arising in the course of operations of most of the leading pharmaceutical firms which need to be resolved by the management of the firm. Many of the leading pharmaceutical companies in India are enlarging their exports to regulated markets in which good markets for drugs going off patent exist in the forthcoming years as in US, Europe and Latin America. Therefore, it is imperative for the companies to maintain adequate risk management practices to improve the quality of products and to meet the regulatory requirements in the countries where the exports are being made.

RISK AND RISK MANAGEMENT

"In good times, it is easy to forget about risk. Optimism abounds when markets are growing and revenue and profits are up. The business is hiring new people, increasing the scale of operations, and searching out new and exciting opportunities for growth. Indeed in such boom periods, the future looks so bright- to paraphrase the pop song-you have to wear sunglasses. Yet, it is in good times that managers need to be most watchful for signs of an impending danger. Such is the paradox of success: It has an uncanny way of setting a company up for trouble; if not outright attack. And not only from outside sources such as competitors or regulators, but from within the organization itself"[2].

The etymology of the word risk is "risicare" from the Italian that means, "To dare". In this meaning, risk is a decision rather than fate. The action we dare to take, which depends on how free we are to make judgments and choices is the essence of management science. Professor Damodaran shares this risk view concept. "In finance, our definition of risk is both different and broader. Risk refers to the likelihood that we will receive a return on an investment that is different from the return we are expecting. Thus, risk includes not only the bad outcomes (returns that are lower than expected) but also good outcomes (returns that are higher than expected)"[3]. In this view, risk and return appear as two sides of the same coin.

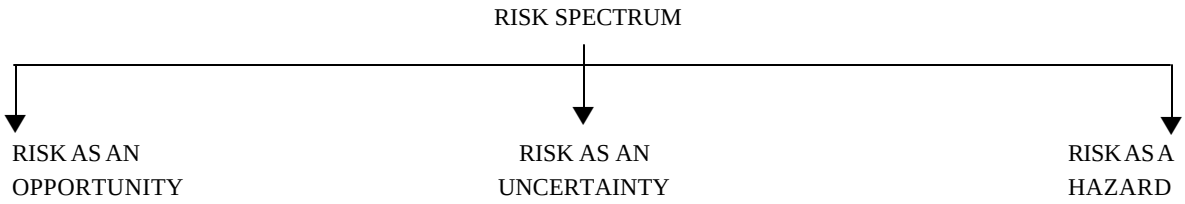
"The concept of risk connotes an adverse outcome one that is to be avoided whenever possible. For businesses, however, the notion of risk takes on more ambiguous and complex connotations. When business managers talk about risk, they may refer to competitive risk, financial market risk, operational risk, technology risk, environmental risk, regulatory risk, legislative risk, sovereign risk and so on. Yet, in many instances, there is lack of clarity surrounding what exactly is meant by risk. Puschaver and Eccles (1996) provide some interesting discussion on the subject of risk. At one end of the spectrum is the view that risk is an opportunity where higher risk gets higher return and vice-versa. On the other extreme is the view that risk is a hazard, implying one that can produce a financial loss. The third definition of risk falls somewhere in the middle of the spectrum and takes on the more academic view of risk as an uncertainty.

In businesses, offensive tactics as well as defensive measures are required for winning. Focusing entirely on defense may help to prevent risks completely, but in so doing, eliminate returns as well. Instead, what is required is an

***Associate Professor**, Aristotle P. G. College, Hyderabad.Email : vyjohn1@yahoo.com

understanding of all the risks that arise from a particular business and then managing these risks effectively. In this context, risk management is a discipline consisting of three distinct dimensions.

- **Upside management:** Creating and capitalizing on opportunities where an institution has distinct advantages to achieve positive gains with improved chances of success.
- **Downside management:** Instituting controls and counter-measures to prevent or mitigate losses as a result of the constraints posed by the organization's operating environment
- **Uncertainty management:** Applying methods and techniques to reduce the variance between anticipated financial outcomes and actual results"[4].



The academic view of risk, i.e., risk as an uncertainty lists the pitfalls that arise in the process of pursuing the goal of wealth maximization. Thus, risks may comprise foreign exchange risk, technology risk, competition risk, operational risk, and price risk, etc.Any one or more of the risk factors may occur and hamper the smooth operations of a firm and may even contribute to financial losses. Recent history points to cases like Barings Bank (1995), Enron Corporation (2001), and the like which have destroyed the wealth of the shareholders due to ineffective risk management mechanisms.

ESSENCE OF RISK MANAGEMENT: "The essence of risk management lies in maximizing the areas where we have some control over the outcome while minimizing the areas where we have absolutely no control over the outcome and the link between the cause and effect is hidden from us"[5]. The ultimate aim of risk management is to make available a consistent stream of cash flows, which result in wealth maximization.

REVIEW OF LITERATURE

The operations of most of the pharmaceutical giants all over the world are facing severe constraints and challenges in manufacturing and marketing various drugs. Given below is an extract from a Pricewaterhouse Coopers research on the global pharmaceutical industry. "The world's largest pharmaceutical companies including Pfizer and Glaxo SmithKline must change their business models to tap a global market that will expand to $1.3 trillion by 2020. The industry strategy of developing so-called blockbuster medicines costs too much and produces too little. The largest companies must stop searching for the wonder drug that will sell for more than $1 billion a year, and focus on drugs with lower sales. US spending on drug R & D, which accounts for 3/4th s of the worldwide investments, hit a record of $55.2 billion in the year 2005-06, and the US-FDA approved about half as many as new treatments as a decade earlier. At the same time, sales and administration expenses climbed 15% in the 10 years to 2005. Its core problem is lack of innovation in making new therapies for the world's most unmet medical needs, the consultants wrote of the industry. The dearth of good new compounds in its pipeline is central to all its other problems including its rising sales and marketing expenditure, poor financial performance and battered reputation. By 2020, India along with Brazil, China, Indonesia, Mexico, Russia and Turkey will account for 70% of the worldwide drug sales. China would be the 2nd or 3rd largest market in the world. Companies must expand their pipelines by looking towards countries where research is burgeoning and redesigning the drug development process. Medicines must be tested on people for effectiveness earlier, guided by better understanding of diseases and so-called biomarkers that indicate how drugs worked. Nearly half of the experimental medicines are proved ineffective, expensive in the late stage clinical trials, the report said.[6]" There was a recent report which clarifies this phenomenon in the Indian context. "While the Indian investment in R & D has been hovering around 1.5-2% of Sales, the foreign multinational companies invest around 15-20% of their sales in R & D. Thus, there is still a long way for Indian pharma companies to go to match up with the resources for R & D available with their global counterparts.[7]" The above observation underscores that there is a shortage of effective R & D, which forms a major risk faced by the pharmaceutical companies all over the world. In the Indian context, due to pricing restrictions and relatively low margins, companies are unable to employ sufficient resources in R & D which forms the backbone of the industry. The existing drugs with all of its volumes of sales contributing to the revenues and the bottom lines of the companies are insufficient to sustain the industry's demand

over a long-term period. So there is a felt need for effective R & D to develop innovative drugs which help cure some of the medical needs like AIDS, lifestyle diseases and other unmet medical needs.

In the domestic market, companies are entering into collaboration or merger/acquisition agreements to differentiate themselves above the rest of the firms and grow aggressively. A lot of consolidation is happening in respect of leading companies in this sector. A case in point is that of Wockhardt Ltd., the renowned Mumbai-based pharma major whose acquisition of French Company for $ 265 million is given in the report below. "Wockhardt on 3rd May, 2007 became the first Indian Company to acquire a non-generic, innovative, overseas Company with 3 patented products and a research base that has the potential to drive future discoveries. Mumbai-based Wockhardt paid $265 million for buying 100% of France's Negma Laboratories, valuing the Paris based firm at 9.7 times its 2006 operating earnings. Negma markets products for osteoarthritis, plebtonic and hypertension therapeutic segments in France and recorded sales of $150 million in 2006. The deal is significant for Wockhardt and possibly for the Indian pharmaceutical industry as it breaks the tradition of local companies targeting only generic drug products overseas. Negma employs original research and develops what are called New Chemical Entities(NCEs) in Industry Parlance. Drug producers such as betapharm (acquired by Dr.Reddy's in late 2005 or Terapia acquired by Ranbaxy) only market generic products, which are off-patent drugs. On the other hand, Negma is an innovative company holding 172 patents and markets 3 new patented products, which account for the largest share of the Company's Sales"[8]. Most recent case, which explains the above phenomena, is given below: "Japan's third-largest drug-maker, Daiichi-Sankyo in the third week of June, 2008 agreed to acquire Ranbaxy's Singhs of New Delhi in an all cash deal valuing India's largest drug maker at $8.5 billion, or over five times its 2007 revenues, the largest deal recorded in the Indian pharmaceutical industry. It will add about $1.6 billion to Daiichi's $8.2 billion top line and give the Japanese pharma major a footprint in over 60 markets, in some of which it is present. While the Singhs will offer 34.8% in the company, a mandatory offer to minority shareholders, if successful, will add another 20% to Daiichi's shareholding, taking it to over 50%. The deal worth $4.6 billion is being concluded at Rs.737 a share, which is a 31% premium to the ruling market price. The combined entity will be bigger than Teva, one of the world's largest generic Company at $9.4 billion, but still far smaller than $40 billion Novartis group, which owns Sandoz, the world's second largest generic player. It will rank No.15 among the list of innovator companies dotted by big names such as $48 billion Pfizer and the $4 billion GlaxoSmithKline"[9].

THE BUYER AND THE SELLER

ELEMENTS	DAIICHI-SANKYO	RANBAXY LABORATORIES
	FY 2007	FY 2007
Net Sales	8220.13	1012.85
Overseas Sales	3349.32	613.87
Research and Development	1527.09	96.47
Operating Income	1464.51	229.91
Net Income	912.52	143.96
Assets	13896.99	527.03
Return on Equity (ROE)	7.80%	28.80%
Earnings Per Share (EPS)	$1.26	$0.35
Number of Consolidated Subsidiaries	43	18
Number of Employees	15,349	8,141
Exchange Rates Used: 1 Dollar = Rs.42.91, 1 Dollar = 107.07 yen	(Figures are in million dollars)	

Source: Company website.

The above reports point to the risk of takeovers and mergers leading to possible integration risk in exploring growth and diversification avenues across the world. It must be the focus of all growth oriented companies to partner with other compatible companies to increase the range of products, capture bigger markets, gain a larger market share, obtain economies of scale and mainly ensure a quicker and effective growth.

A recent report states clearly that "Though the Indian Pharmaceutical industry is the 5th largest in the world in terms of volume terms, due to the low price realizations (primarily due to price controls by the government), the global share of the Indian market value in terms of value is a meager 1%, making it the fourteenth largest in the world."[10] Most of the large and medium companies complain that their margins are affected due to price control on essential drugs monitored by the Government through the National Pharmaceutical Pricing Policy and the Drug Prices Control Order, 1995. These price controls impose a serious price risk to the firms. Since the firms cannot increase the prices of the drugs, a majority of which are essential drugs in much demand and controlled by the government, the operational

costs of the firms need to be tightly controlled. For instance, there was a recent report that many graduates in the area of pharmaceuticals and life sciences are getting employed in the BPO and the KPO sectors as the salaries offered by those companies are higher than those offered by the pharmaceutical companies.

Many small and medium enterprises in the pharmaceutical sector are not doing well. The following report explains the point "The success of the KPO and LPO segments has turned out to be a bane for the pharma sector (especially for the SMEs) which is facing manpower crunch. Pharma companies are facing high attrition rates of 25-30%."[11] There are other issues that the pharma SMEs are to contend with. They are worse off as they also have to grapple with issues like limited resources and heavy expenses in marketing. There are also reports that due to the Central Government recently declaring J & K, HP and Uttaranchal as tax-exempt states for pharma companies to set up their plants, many companies particularly from Maharashtra and Gujarat have migrated to these States. Since the companies are exempt from Excise Duties in the states mentioned above, there is a difference in (MRP) fixed by them and companies in other states. This is hitting the sales of firms in states like Maharashtra and Gujarat, which are among the biggest contributors - Rs.6000-Rs.7000 crore in the domestic pharma market which is at least in the range of Rs.25000 crore and above. Thus, the price control, exercised directly and indirectly by the government acts as a serious deterrent and a handicap to the companies. Companies are unable to control raw material costs too as their prices are constantly increasing. This is more so if the raw materials are in the form of intermediates which have to be imported from countries like China. There are twin disadvantages here. One is the rise in the raw material cost per se and the other is the foreign exchange rate, which may depreciate and result in huge payments. Thus price risk has ripple effect and causes huge regulatory and operational risks. A good number of companies particularly those manufacturing APIs with the help of intermediates imported from China have complained that they will be forced to shut down their operations if the regulatory authorities do not come to their rescue. Many representations are being made by the pharmaceutical companies associations like the IDMA(Indian Drug Manufacturers' Association), Mumbai and BDMA(Bulk Drug Manufacturers' Association), Hyderabad to restrict the price controls so the companies are not affected adversely. The SMEs in the pharmaceutical sector face pressures from the regulators, i.e., the government exercising control through pricing, taxation, rigid and dogmatic administrative mechanism which is insensitive and inflexible to the needs of the players in the industry and to the changing dynamics which require timely changes in regulations which avoid adverse impact on the firms and contribute to the healthy growth of the industry.

Apart from the above mentioned factors, it is well noted that in India, most of the large companies face regulatory and compliance risks from the regulatory bodies in different regions all over the world. Pharmaceutical firms are regulated by multiple regulatory authorities in foreign countries into which they export like regulatory authorities in USA, i.e., Food and Drug Administration (USFDA), USA, Medicines & Healthcare Products Regulatory Agency (MHRA) UK, Therapeutic Goods Administration (TGA), Australia, European Directorate for the Quality of Medicines (EDQM-EU), Medicines Control Council (MCC), South Africa, Pharmaceutical Inspection Convention (PIC), Germany, etc., companies in India need to have their operations, i.e., basically people, processes, technology and systems in place to meet the regulatory requirements of the above bodies.

OBJECTIVES, SCOPE AND METHODOLOGY OF THE STUDY

1) OBJECTIVES OF THE STUDY:

A) Identify the potential risk factors influencing the pharmaceutical industries in India.

B) Identify the dominant risk factors influencing the pharmaceutical industry in India.

2) SCOPE OF THE STUDY:

The study identifies the key risks faced in general by the pharmaceutical industries in India. The study focuses primarily on medium to large-scale industries located in and around Hyderabad, Solapur, Pune and Mumbai. Since the study is an exploratory and descriptive one, it makes a sincere effort to explain the current status of the risk management practices, which are being followed by pharmaceutical enterprises in India.

3) METHODOLOGY OF THE STUDY:

The secondary data for the purpose of the study was obtained from the business periodicals and journals like Economic Times, Business India, Business World, Harvard Business Review and some of the websites of the leading companies. Apart from the above sources, the publications and literature obtained from the following sources were also used:

i. Indian Drug Manufacturers Association, Mumbai. ii. Bulk Drug Manufacturers Association, Hyderabad.

iii. Ministry of Chemicals and Fertilizers, Government of India. iv. Express Pharma

v. Annual reports of companies.

An effort was made to collect primary data using qualitative and observational methods comprising individual

in-depth interviews, non-directive interviews, expert opinions and focused individual interviews. The objective was to identify the dominant risk factors influencing the pharmaceutical industries in India. The above information was gathered from about a little more than ten experts in the industry. It was gathered from eminent managers, consultants in Indian and foreign multinational companies and the US Food and Drug Administration (USFDA) officials. They were resource persons who spoke during the "Workshop on Risk Assessment" conducted by the Indian Drug Manufacturers' Association (IDMA), on 15th September, 2006 and also during the Tenth Pharmaceutical Analysts' Convention conducted by IDMA at Mumbai on 21st and 22nd November, 2006 both of the events in which the researcher was privileged to participate.

RISK ANALYSIS IN PHARMACEUTICAL INDUSTRIES IN INDIA

Risk analysis and management in the pharmaceutical industry in India is a different exercise compared to that of other industries. "India's present budgetary allocation is just 1% of the GNP towards the health-care sector. There should be a substantial scale-up in this figure and the government should look to providing at least 4% of the GNP for tackling the healthcare issues. Given the Indian lead in strategic sectors like education, IT and communications, the government should make sincere efforts to scale-up operations in the health-care sector."[12] There are special nuances in this sector like the excessive price controls in indigenous market, global consolidation, presence of counterfeit drugs, compliance with global standards and long drawn process of research. It takes about 10-12 years for the discovery and development of a new medicine and the average effective patient life for a new drug is roughly less than 10 years. The cost of developing a new drug can be in excess of $1 billion. That is because only 1 out of 10 drugs that start human clinical trials reach the market. The Indian industry is subject to many risks as it is functioning amidst such constraints which ensures that the fittest survive. Among the plethora of risks influencing this industry, given below is a brief view about the taxonomy of risks influencing this sector and the dominant risks among them.

TAXONOMY OF RISKS INFLUENCING PHARMACEUTICAL INDUSTRY IN INDIA

To examine the possible risk factors influencing the pharmaceutical industry in India was a difficult task because while some risk factors were common to all companies, risk factors of individual firms did vary depending upon the scale of operations, range of products, number of geographical markets in which the firm was able to market its products, pricing of products, the relevant legal controls, the management philosophy , controlling stakeholders in the company, employee training, motivation, efficiency levels and a host of other factors.

Summarizing the review of literature, views noted from eminent managers and consultants, we can conclude that the following is the taxonomy of risks influencing the firms in the industry.

1) **FINANCE RISK:** • Price Risk. • Foreign Exchange Risk. • Taxes Risk.
2) **RESEARCH AND DEVELOPMENT RISK:** • Stagnation Risk.
3) **REGULATORY RISK:** • Compliance Risk.
4) **MARKET RISK:** • Competitor Risk. • Country Risk. • Geographic Risk. • Supply Chain Risk.
5) **QUALITY RISK:** • Contamination Risk. • Mislabeling Risk.
6) **STRATEGIC RISK:** • Business Portfolio Risk. • Integration Risk (in case of mergers & acquisitions). • Reputation Risk. • Vision Risk.
7) **TECHNOLOGY RISK:**
8) **OPERATIONAL RISK:** • People Risk. • Process Risk. • Systems Risk.

CONCLUSION

Out of the taxonomy of eight major risk factors identified above, the information sought posits that the dominant risks influencing the Indian Pharmaceutical industry are those mentioned below:

1) REGULATORY RISK: • Compliance Risk.

Companies in India need to maintain quality assurance systems which meet the regulatory requirements of the authorities around the world. Thus, Compliance risk constitutes effective maintenance of existing systems which facilitate quality control on drugs.

2) QUALITY RISK: • Contamination Risk. • Mislabeling Risk.

The hallmark of a drug is its efficacy in healing the particular ailment for which it is made. Hence, effective quality control makes it imperative to produce contamination-free drugs at each stage of manufacturing. Drugs should also be ensured that they are labeled appropriately.

3) OPERATIONAL RISK: • People Risk. • Process Risk. • Systems Risk.

Too often, the onus of effective operations lies with the people at the helm of operations. People at all levels must be conversant with proper risk management practices. The processes and systems must also be dovetailed to meet the needs of the target markets.

LIMITATIONS OF THE STUDY AND FUTURE RESEARCH

1) LIMITATIONS:

1) Since many of the leading pharmaceutical companies in India depend on global markets for their export revenues, comprehensive risk management practices do exist in most of the large companies. But in case of many other companies, they need to be contemplated and developed.
2) Since the information sought is confidential, the scope of eliciting information is limited.

2) FUTURE RESEARCH:

Much research on the dominant risk factors mentioned above waits to be done in order to explore the most appropriate tools with which they could be mitigated.

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