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Investment Risk Identification and Its Assessment: A Study of Indian Pharmaceutical Sector

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Abstract

The pharmaceutical industry is undergoing rapid transformation, as the pharmacy companies are facing pressure from governments and public for reduction in prices of life-saving drugs and initiating outcome-based pricing. India's pharmaceutical industry has been growing at record levels from past ten years. Even though the sector has a very huge potential to grow, from last couple of years it is facing major loss as there is a dip in investments due to sector specific risks as legal, safety, market to name a few. This industry's deep-rooted position as a global leader in the production of high-quality generic medicines is set to harvest significant new benefits as the patents on a number of blockbuster's drugs are about to expire over the next few years. Safety, policy, regulatory, contingency planning, various investment risks identified in this paper which are involved in the pharmaceutical, lead to fall in investments. The severity impact of all above identified investment risks on investment is analysed using factor analysis. Most influential risks are enumerated and simultaneously presented using graphical method as tornado chart

Keyword: Pharmacy Sector, Risk Identification, Impact Assessment, Risk Mitigation

Introduction

The contribution of pharmaceutical sector in India's GDP is 14.4 % (Prentis, Walker, Heard, Tucker, & Wiley, 2009). The Indian pharmaceutical industry has a bright future contributing towards GDP with an expectation of 20% by 2025 (Shafiei, Ford, Morecroft, & Lisboa, 2013). Varied functions like bulk drug manufacturing, contract research, clinical research, research and development pertained to vaccines, are the major strengths of it. Multinational pharmaceutical corporations outsource these activities and help the growth of the sector. Indian pharmaceutical industry ranks 3rd in the world pertaining to the sales volume and the estimated worth of the Indian pharmaceutical industry is US$ 6 billion and growth rate of the industry is 13% per year (Edwards & Chakraborty, 2012). Almost 70% of the domestic demand for bulk drugs is handled by the Indian Pharmacy companies which produces around 20% to 24% of the global generic drugs (Shafiei *et al*., 2013).

The major factors responsible for this growth are increased sales of generic medicines, continued growth in chronic therapies and better penetration in rural markets (Grabowski & Vernon, 1990); (Abzakh, Ling, & Alkilani, 2013). The Ministry of Commerce has set a target to Indian pharmaceutical sector that it should export US$ 25 billion worth drugs by 2017 at an annual growth rate of 25% (Edwards & Chakraborty, 2012).

Growth in the pharmaceutical market has been declining from the higher double digits to single digit over the past few months in line with the country's GDP, which has also shown a crash over the past few quarters. The reasons for this degrowth is identified due to multiple policy & regulatory issues (Alkhateeb, Clauson, Khanfar, & Latif, 2008). Growth declined from 5.3% in November to 4.3% in December last year, recovering to 10.8% in January this year. But it again dropped to 7.9% in February, and further to 5.6% in March this year (Shafiei *et al*., 2013). Despite having huge potential in Pharmacy sector, it is crossing turbulence. The reasons for these fluctuations were identified by Alkhateeb *et al*. (2008),

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Anderson, Pharmaceuticals, Scannell, Devices, Pharma, and Bernstein (1994), Edwards and Chakraborty (2012), Grabowski and Vernon (1990) as policy restructuring in pharmacy industry, safety issues, R&D modification, technical issues and few more risk factors which are giving diminishing returns to this sector. In order to explore major investment risk factors this paper contribute towards pharmaceutical sector by analysing investment risks involved in this specific sector which lead to fall in investments. It also explores the impact of existing risks over various investment. This paper also advised policy makers, investors, stake owners about investment issues and accordingly they suggest mitigations to overcome the issues.

Literature Review

Investment decision-making is an important part of strategic decision-making in every firm because new investment projects essentially affect future economic results and the firm´s prosperity. Success of new projects contributes in a impressive manner to the growth of enterprise´s efficiency

Anderson *et al*. (1994) check the impact oninvestment decision using probabilistic mental model in which experiments were conducted in pharma sector to test whether different types of risk information given in a time sequence will influence the decisions of investors positively or negatively. Reepmeyer, Gassmann, and Rüther (2011) in thier study of pharmacy sector risk identification, identified as 0.76 positive correlation between investors confidence and their information gathering ability, thus indicating that investors' confidence enhances the development of the ability to gather investment information. Kida, Moreno, and Smith (2010) examined whether individuals investment decisions are affected by choice set size (limited vs. extensive choice set) and whether the effect is mitigated or changed for individuals who are more experienced with investment decisions.

Prentis *et al*. (2009) proposed national drug pricing policy will cost drug manufacturers around INR 1,500 crore and distrubutors and traders collectively over INR 2,500 crore in revenue loss on its approval. This pricing policy affects badly on new investments as the change in margin shows a great variation (Palnitkar, 2013). Indian companies were facing dilemma whether to invest or not (Sharma & Chaitanya, 2013). US Food and Drug Administration (FDA), on their visit to Ranbaxy Laboratories factory in January 2008, were stunned by unashamed violation of the FDA's current good manufacturing practices (cGMP). Dey (2013) in his article talks about how quality issues affect investment in Indian pharmaceutical sector.

Risk Identification in Pharmacy Industry

Burgenson (2005) defined risk as a combination of probability of occurrence and severity of that harm and it's measure of potential ability to accomplish overall programme objectives within specified costs and performance criteria. Iyer, (2011) defined risk in opportunity, which is where the profit is effectively identified, controlled and managed so that business thrives.

Khaled and Abzakh (2013) highlighted the impact of perceived risks in their paper. Uncertainty caused by consumer's inability to anticipate the consequences of their purchase decisions is called perceived risk. Consumers trust over pharmacy industry is varying which impacts investors also. Bio-diversity and eco system are rising as a systemic risk for pharmaceutical companies in the same way as climate change (Grabowski & Vernon, 1990). It is not yet clear how significant an issue this is for the pharmaceutical sector. It also discussed various issues associated with other dependencies like water and supply chain risks, which could also cause a risk for the sector.

Lowmana and Trottb (2010) discussed an excellent example of a research and technology intensive industry where outsourcing has led to problems in the innovation and new product development process, operational and technological variations in pharmacy industry was a major area of concern. Spiker (2003) talks about several types of risk encountered in drug discovery, development and marketing, as well as the overall business risks in the pharmaceutical industry. Discovery risk refers to the risk companies face if they are partly or totally dependent on discovering new drugs and many approaches were provided for companies to pursue in order to decrease discovery risk.it also covers majorly on safety risk under which safety of personal and environement was considered.

Generics will continue to rule the market while patent protected products are likely to represent 10% of share

till 2015 (Kumra, Mitra, & Pasricha, 2013). There is a strong co-relation between the domestic pharmaceutical market and country's GDP. The sources of finance for the expansion and diversification of industry play a significant role, so financial risks also play an optimum role in this regard.

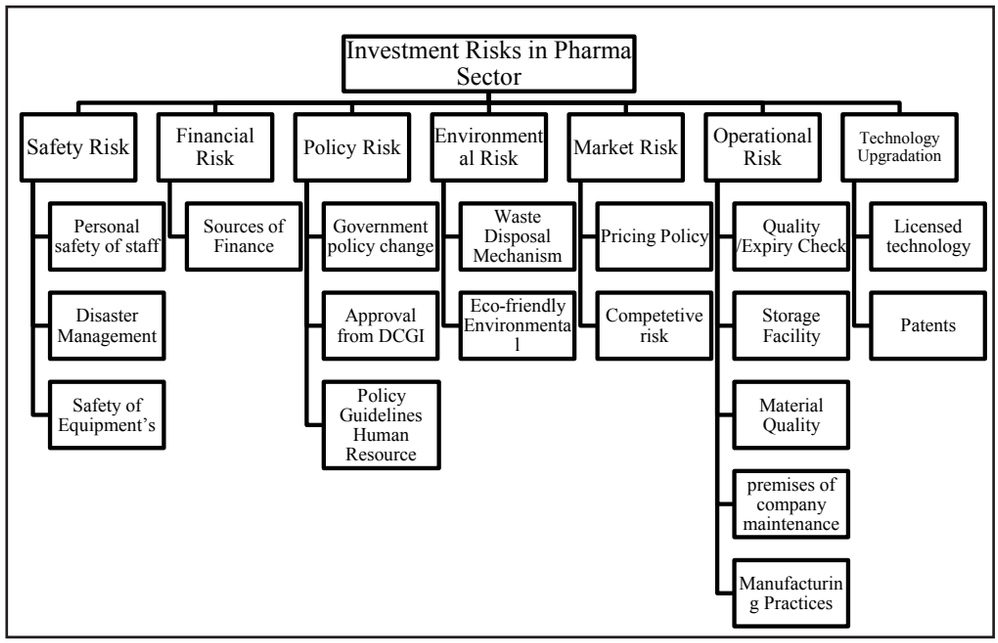

Fig. 1: Investments Risks in Pharmaceutical Industries

Rajgopal (2013) measured how the changes in regulations showed negative effect on Indian pharmaceutical sector. Singh (2013) stated that drug maker GlaxoSmithKline Pharmaceuticals' loss has been nailed at INR 137Cr while that of Ranbaxy Laboratories is estimated to be INR 115Cr. Other big drug makers such as Abbott India, Zydus Cadila, and Sanofi Aventis are projected to lose over INR 50 Cr. Even the drug makers are planning to reduce their fixed investments on research & development which is a big loss to pharma industry as a whole.

Budhbhatti (2013) stated that drugs worth $235 billion are expected to go off patent in the next five years, leaving the market open for off patent or generic drugs which will be great loss to pharmaceutical industry and global spending on medicines will reach 1.1 trillion dollar by 2020. Kodgule (2011) opine that the core strength of Indian pharmaceutical sector today is its huge export potential. The industry is making adequate returns from the domestic sales but bulk of its profits come from the export of generics and active pharmaceutical ingredients to the developed markets. Moran (2012) comment that in the year 2012, patent cliff reaches its height with $33 billion of sales at risk but the impact of loss of exclusivity will continue to bounce across the decade, with more than $290 billion of prescription drugs sales due to be exposed to generic competition between now and 2018. All risk which are identified are categorised into 6 major themes as safety, policy, financial, technological, market, & operational risk as shown in Fig. 1.

Risk Assessment Current Practices

Risk assessment is an important step of risk management process. Risk assessment's various theories for investment decision-making are distributed in deterministic, probabilistic, stochastic, and strategic approaches. Neo-classical approach of investment decision follows cash flow change in a deterministic way over time. It is also known as NPV method. It reduces financial and economic constraints leading to a single value (NPV) for decision-making. It does not incorporate the risk of uncertainty to the future cash flow.

Probabilistic approach inputs for CBA, thereby addressing future uncertainty. Hence it captures more

information about project feasibility than using single NPV, gives information about project risk, and partially this is reversible decision in worse case situation (Kalantzopoulos, Hatzigeorgiou, & Spyridis, 2008) (I, 2007). DTA is useful tool for strategic decision-making in the presence of uncertainty (considering the uncertainty). It can take sequential feasibility test and decision as opposed to NPV analysis focused on initial accept or reject. The major flaw is with increasing number of paths decisions increase in geometric progression which yield big analytical challenge in choosing the right decision.

Popular technique for examining the effect of uncertain inputs is sensitivity analysis, where a given output is calculated for various inputs. One more step ahead in this series is a more sophisticated scenario analysis where jointly using multiple variables together most likely, pessimistic and optimistic scenarios are created. Such scenarios can also be assigned explicit probabilities and be represented as decision trees analysis, (Castaldi, Chastain, Windram, Ziatyk, & Sciences, 2003(Castaldi et al., 2003a); Morgan, Apt & Lave, 2005). Scenario analyses yield discrete output instead of probabilistic range derived from Monte Carlo simulation and prefer discrete output as this has more practical use which incorporates more risk factors (Cabral, Júnior, & Reid, 2010; Roy, 2012)(Firestone, Fenner-crisp, Chang, & Callahan, 1997)(Rode & Dean, n.d.). (Kalantzopoulos et al., 2008)Strategic approach is based upon objective function maximisation and solution for optimal time of investment through dynamic programming method (Mittal, 2004). The objective function can be used either DCF or ROV. A dynamic programming approach is adopted and the timing of the irreversible investment formulated as an optimal stopping problem (Karatzas & Shreve, 1991).

All of the above methods account for the financial impact of the chosen alternatives. The consumer theory based approaches do not take into account the financial aspects of the new product development and analyse consumers' preferences for different product alternatives instead (Simchi-Levi, 2010). Risk mitigation strategies for controllable risks are those which a global supply chain can apply to address these global risks: speculative, hedge and flexible strategies. Basic risk management facilitation methods (flowcharts, check sheets, etc.) include failure mode effects analysis (FMEA), failure mode, effects, and criticality analysis (FMECA), fault tree analysis (FTA). This study helps the pharmaceutical companies to overcome the losses due to various internal and external industrial risks and also helps in guiding the pharmaceutical companies to meet the quality and safety of society through their products, to attract more investors and promote private investments, and to avoid impact of sector loss on government revenue. Considering the above facts the central argument of the paper revolves around two objectives which are discussed below.

Objectives

1. To identify various investment risks involved in pharmaceutical sector.
2. To assess the impact of all identified investment risks on investment in Pharmaceutical sector.

Research Methodology

The objective of the study can be accomplished by conducting a systematic[1] approach in order to solve the research problem. This study is conducted using the exploratory research, wherein a large amount of data is being collected and after careful mining of data the information thereby being obtained is used to provide an understanding and a conclusion.

Initially in order to identify various risks available in pharmacy industry extensive literature review from various pharmacy industry related journals and relevant reports were considered for study. From those literatures major factors were identified which cause risk in pharmacy industry. In order to see the commonality of these global risk factors for Indian context, validation of those factors were performed using primary discussion with experts of pharma industry, after validation the closed ended questionnaire was prepared for impact assessment.

Responses have been collected by using closed ended questionnaires, where almost 300 people were selected for data collection through convenience and judgemental sampling, and after data mining 137 respondents responses were identified (who belong to pharmacy industries i.e.

1A systematic approach is a process used to determine the viability of a project or procedure based on the experiential application of clearly defined and repeatable steps and an evaluation of the outcomes. The goal of a systematic approach is to identify the most efficient means to generate consistent, optimum results.

managers, employees, investors) for analysis.

Non-probabilistic judgemental sample is used for data collection due to limitation of availability in expertise in this area. In this study author used factor analysis for impact assessment of various identified factors through literature review. Sensitivity analysis as tools is used to analyse the sensitivity of all these factors over others. Factor analysis is used as data reduction tool, which removes duplication from a setoff correlated variables and factors which are independent on one another.

These factors explain most part of variations of the original set of data, and collected data through questtionaire is subjected to SPSS SOFTWARE and anlysed using factor analysis under descriptive reduction where strings variables are avoided and numeric data is considered. Initial solution under statistics, KMO and Bartlett's test of sphericity, coefficients, significance levels under correlation matrix is used to present the results.

Data Analysis

The analysis of this paper is segregated into two major segments whereas, identification of risk factors were performed using literature review which was discussed in previous section. For impact assessment of identified risk factors factor analysis was used where the exact impact of various factors was examined using subcomponents of factor analysis highlighted in below mentioned section.

Risk Assessment in Pharmaceutical Sector

Correlation Matrix

This correlation matrix gives the correlations between the original variables. Before performing a principal components analysis based on questionnaire responses. If the correlation between any of the two variables is too high (above 0.75), it is considered as impactful risk. As the two variables seem to be measuring the same thing, the whole point of the analysis is to reduce the number of items (variables). From our output, the correlation between any two components is not more than 0.75, so all the variables considered in the analysis are independent and acceptable for factor analysis. Communalities table (Table 1) shows the extraction of various responses on questionnaire. Table 1 explains the proportion of each variable's variance that can be explained by the principal components.

Table 1: Communalities

	Initial	*Extraction*
Competitors acquiring your company	1.000	.434
premises of company maintenance	1.000	.490
Manufacturing Practices	1.000	.248
Personal safety of staff	1.000	.356
Policy Guidelines human resource	1.000	.666
Safety of Equipment's	1.000	.591
Technological up gradation	1.000	.421
Eco-friendly Environmental	1.000	.372
Material Quality	1.000	.379
Waste disposal Mechanism	1.000	.195
Licensed technology	1.000	.478
Quality Check	1.000	.394
Approval from DCGI (drug controller general of India)	1.000	.725
government policy change	1.000	.514
Pricing Policy	1.000	.210
Sources of Finance	1.000	.192
Storage Facility	1.000	.324
Expiry Check	1.000	.333
Patents	1.000	.351
Disaster Management	1.000	.468
Extraction Method: Principal Component Analysis.		

Preceded by communality analysis, principal component analysis was conducted on our study data. From our communality output, communality for the first variable is 0.369 which is nothing but 36.9% of variance of the first variable namely age of respondent. It is explained by 4 factors in component matrix (summation of squares of correlation values horizontally in correlation matrix).

Total Variance Explained

In Table 2 total variance is explained; components which have initial Eigen values more than 1 are considered as major factors. In output, 10 variables have more than 1 as their Eigen value but out of 10 variables only four are considered to be our major factors, as they are showing greater variation while rest are showing less variance as their values are close to each other.

There are as many components extracted during a factor analysis as there are variables put into it. In our study, we have used 27 variables. Eigen values are the variances of the principal components. Though research is conducted

as factor analysis on the correlation matrix, the variables are standardised, which means that each variable has a variance of 1, and the total variance is equal to the number of variables used in the analysis. This total value shows the Eigen values. The first component will always account for the most variance (and hence has the highest Eigen value). In this study, first component results 3.796, and the next component will account for as much of the left over variance as it can, and so on. Hence, each successive component will account for lesser variance. The percent of variance accounted for by each principal component in this study decreases gradually. The first component is contributing the maximum variance of 14.061% and this decreased gradually. After first four components, the rest showed very less variance. Cumulative percentage contains the cumulative percentage of variance accounted by the current and all preceding principal components. For example, the fourth row shows a value of 39.770. This means that the first four components together account for 39.770% of the total variance. Extraction sums of squared loadings reproduce the values given on the same row on the left side of the table. The number of rows reproduced on the right side of the table is determined by the number of principal components whose Eigen values are 1 or greater. The ultimate variance showed by the four components was same with or without rotation.

Table 2: Total Variance Explained

Component	*Initial Eigenvalues*			*Extraction Sums of Squared Loadings*			*Rotation Sums of Squared Loadings*		
	Total	*%of Variance*	*Cumulative %*	*Total*	*% of Variance*	*Cumulative %*	*Total*	*% of Variance*	*Cumulative %*
1	3.796	14.061	14.061	3.796	14.061	14.061	3.191	11.817	11.817
2	2.890	10.705	24.766	2.890	10.705	24.766	2.809	10.402	22.219
3	2.189	8.108	32.873	2.189	8.108	32.873	2.651	9.820	32.039
4	1.862	6.897	39.770	1.862	6.897	39.770	2.088	7.732	39.770
5	1.701	6.302	46.072						
6	1.593	5.902	51.974						
7	1.485	5.501	57.475						
8	1.281	4.743	62.218						
9	1.097	4.064	66.282						
10	1.050	3.890	70.172						
11	.959	3.553	73.725						
12	.867	3.212	76.938						
13	.726	2.689	79.627						
14	.650	2.407	82.034						
15	.633	2.344	84.379						
16	.582	2.157	86.536						
17	.559	2.071	88.607						
18	.509	1.884	90.490						
19	.407	1.507	91.998						
20	.405	1.499	93.497						
21	.378	1.400	94.896						
22	.322	1.191	96.088						
23	.284	1.052	97.140						
24	.273	1.010	98.149						
25	.194	.718	98.867						
26	.179	.664	99.532						
27	.126	.468	100.000						

Component matrix contains component loadings, which are the correlations between the variable and the component because these are correlations, possible values range from -1 to +1. To make it easy specific range can be given so that lower correlations can be removed which are probably not meaningful anyway. Component under this heading are the principal components that have been extracted. In our study four components were extracted. In order to interpret the results in a better way a factor rotation is desired.

Table 3: Rotated Component Matrix

	Component			
	1	*2*	*3*	*4*
Competitors acquiring your company	-.284	.498	.141	-.084
Premises of company maintenance	.199	-.066	-.259	.568
Manufacturing Practices	.404	-.051	.564	-.081
Personal safety of staff	-.384	.259	.059	.173
Policy Guidelines human resource	.531	.107	.236	.087
Safety of Equipment's	-.203	-.533	.542	-.217
Technological up gradation	.762	.082	.067	.014
Eco-friendly Environmental	.213	.436	.312	-.270
Material Quality	.528	.158	.128	-.318
Waste disposal Mechanism	.583	.146	-.062	-.079
Licensed technology	-.028	-.043	-.262	-.555
Quality Check	.363	-.006	.252	.011
Approval from DCGI (drug controller general of India)	-.024	.016	.111	.682
government policy change	.211	.375	.456	.033
Pricing Policy	-.149	-.305	.736	.262
sources of Finance	.074	.698	.137	.050
Storage Facility	.044	.101	.413	.097
Expiry Check	.170	.331	.458	-.080
Patents	.504	.170	.189	.073
Disaster Management	-.065	-.393	-.177	.401
Age of respondent	-.022	.630	-.253	.001
Gender of respondent	-.167	-.015	.209	.629
Extraction Method: Principal Component Analysis. Rotation Method: Varimax with Kaiser Normalisation.				
a. Rotation converged in 9 iterations.				

Varimax rotation is used which results in independent factors. Purpose of rotation is to have the factor loadings in such way that they either close to zero or -1 or +1, which means factor loadings are high on some variable and low on some other variables. In order to interpret the results a cut-off point has to be decided generally 0.5 is taken. Output comes after varimax rotation, considering four components. Components which have more than 0.5 as their correlation score (factor loading) with variables are sorted out and given a common name which will be name of component. From our component matrix output, all higher factor loadings for every variable have been found and to the end, each component gets certain number of variables with high factor loadings which cumulatively define that particular component as certain risk in the industry.

Among all the variables, impact on the safety risk is showing major impact of 0.762 which is related to location safety of manufacturing unit. Hence, safety risk in pharmaceutical industry is very high because pharmaceutical products need to be manufactured at very high hygiene locale. As per DCGI all pharmaceutical companies need to follow GMP (good manufacturing practices) to retain their license in active. This is the major regulation which every pharmaceutical company should follow to deliver good quality medicines.

Political risk: Out of all variables, showing impact on factor loading is 0.669 which is related to political scenario in the country. Pharmaceutical companies are affected by policy changes quickly. The current scenario in the Indian pharmaceutical industry is the proposal of new drug pricing policy which has badly affected the government revenue from the industry. This proposal is about change in pricing the drugs from old cost-based pricing method to weighted average pricing method. This method is beneficial to public but pharmacy companies have to face the loss.

Regulatory shows impact of 0.727 which is posed on pharmaceutical companies in the country. DCGI is a statutory body, which holds control over all pharmaceutical companies. Pharmaceutical companies need to meet the required criteria and get approval from DCGI to start manufacturing processes which is not so easy as the FDA has come across some unashamed violation of current goods manufacturing practices by Ranbaxy Laboratories limited, India at their Dewas and Paonta Sahib plant in Himachal. They got a ban on 30 generic drugs, for which Ranbaxy Laboratories limited, India was asked to pay a penalty of INR 2,800 Cr. Government is very stringent at regulations on pharmaceutical companies which shows great effect on pharma companies.

Contingency is viewing major impact of 0.576 which is related to risk involved improper contingency planning in pharmaceutical companies. Pharmaceutical manufacturing units are high investment projects where the need of contingency plan for raw materials or locale security is very high. An unexpected event of fire accident which is quite commonly occurring accident may cause severe damage to both operational personnel and company revenue.

Result

Kaiser-Meyer-Olkin Measure of Sampling Adequacy

This measure varies between 0 and 1, and values closer to 1 are better. A value of 0.5 is a suggested minimum.

Table 4: KMO and Bartlett's Test

Kaiser-Meyer-Olkin Measure of Sampling Adequacy.		*.654*
Bartlett's Test of Sphericity	Approx. Chi-Square	837.859
	Df	351
	Sig.	.000

From the output KMO measure is 0.654 which is in significance zone more than 0.6 and Bartlett's Test of Sphericity is also satisfied with almost less p value which is evident from Table 4.

Scree Plot

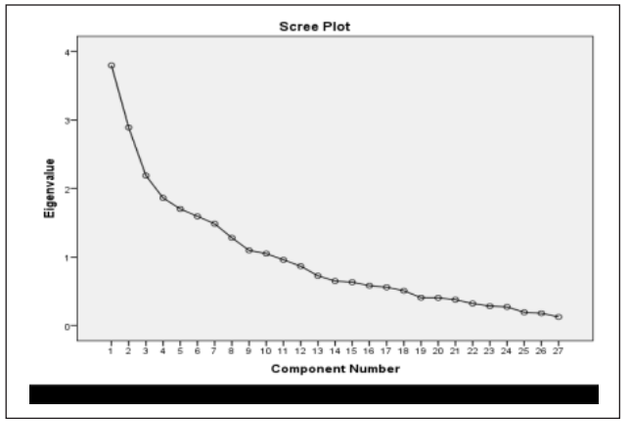

Fig. 2: Scree Plot for Factors

Fig. 2 shows the Eigen values on the y-axis and the number of factors (components) on the x-axis. It always displays a downward curve. The point where the slope of the curve is clearly leveling off (the elbow) indicates the number of factors that should be generated by the analysis. If you look at the graph, the first four factor loadings are showing greater variance, rest are very close. This indicates first four factors are impacting majorly and differentiable rest are clustered.

Sensitivity Analysis

Sensitivity analysis is the study of how the uncertainty in the output is distributed. Sensitivity analysis is very useful when attempting to determine the impact the actual outcome of a particular variable will have, if it differs from what was previously assumed. Author had used tornado chart in this study to perform sensitivity analysis it compares the relative importance of variables and the sensitive variable is modeled as uncertain value while all other variables are held at stable. From this research, author had found out four major risks which are represented by tornado chart which represents the greater risk with longer bar.

In tornado chart it is visible that safety risk is more prominent risk in pharmaceutical industry.

From the study, following are found through various analysis tools (factor analysis & sensitivity analysis) which give an understanding about risks involved and impact of those on the pharmaceutical sector When correlation matrix was obtained through SPSS, it indicates that data we used in our study are independent and acceptable for factor analysis because the correlation between any two different components is not more than 0.75. Author got Kaiser-Meyer-Olkin Measure of Sampling Adequacy measure as 0.554 and Bartlett's Test of Sphericity is significant which indicate data we are using for study is eligible for performing factor analysis.

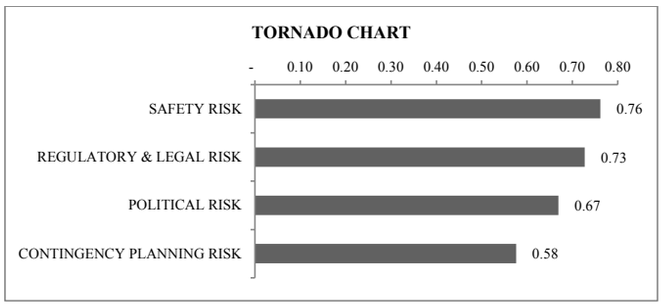

Fig. 3: Tornado Chart for Risk Factors

On factor analysis total 10 variables have more than 1 as their Eigen value. We considered only four as our major factors, as they show greater variation; rest show less variance as their values are close to each other which is clearly observed in scree plot. When scree plot was drawn, a perfect slope with clearly leveling off curve was obtained indicating analysis was done perfectly. From the total variance explained, we have identified that first four components together account for 39.77% of the total variance.

Based on factor analysis it was concluded to an understanding that there are four major risks involved in pharmaceutical industry; they are safety risk, political risk, regulatory/ legal risk, and contingency planning risk. Sensitivity analysis, was represented through tornado chart where safety risk refers to the safety of human life and is the most prominent risk involved in Indian pharmaceutical industry. Through literature review, we have identified some risks like bio-diversity risk, patent risk, drug discovery risk which deal with expense on R&D in finding a new drug whose result is uncertain. Performance risk occurs when purchased product might not perform as the consumer expects, so it will not deliver the benefits as perceived.

Conclusion and Discussion

Pharmaceutical companies should primarily look into human resource whose safety and knowledge levels are very much needed to deal in quarantine area where the drugs are manufactured. Pharmaceutical companies need to maintain healthy relation with government to avoid political risks, so that government could help in better projects by showing its presence through some investment from its side. Pharmaceutical companies, to avoid regulatory and operational risks, must be punctual and should make as its work culture in following GMP (good manufacturing practices). To encourage private investments, pharmaceutical companies could project their certifications and cost efficient production/process methods. Pharmaceutical companies need to have an outstanding contingency plan to overcome any sudden uncertainty like fire accidents. Being manufacturing sector, work of pharmaceutical companies is highly based on machinery which is long term investment from the company side, so they should carefully look about its wear and tear. To overcome environmental issues pharmaceutical companies should be careful in dumping methods of its chemical wastes and its usage of water should be adequate. Companies should carry out a comprehensive risk assessment of BES issues, addressing use of active ingredients from nature in drug discovery and development. Direct operational footprint of manufacturing sites and sourcing of inert and active

ingredients' greater disclosures on implementation of position statements and policy commitments, in particular on the management of various risks and impacts in raw materials sourcing, would provide greater assurance to stakeholders that risks are being effectively managed.

This paper is contributing to the pharmacy sector by finding out various ignored or hidden risks apart from known risks involved in the pharmaceutical sector and their impact. It also suggests few risk mitigation steps to encourage investments into the sector. It was identified that there has never been so important time for India's government and its drug producers, both multinational and domestic, to work together for the welfare of the industry and the nation. With its huge advantages, including a large, well-educated, skilled and English-speaking workforce, low operational costs and improving regulatory infrastructure, India has the potential to become the region's biggest hub for pharmaceutical and drug discovery research, manufacturing, exporting and health care services within few years.

However, in order for this to happen, it is imperative that the regulatory environment continues to improve. Otherwise, India needs to look to the achievements of other countries, where the government's strong commitment pro-industry policies have produced a positive environment that not only offers drug manufacturers a product patent regime but also, and crucially, data protection. India's continuing failure to do so needs to be urgently rectified. The goals set out in the Indian government's draft National Pharmaceuticals Policy in terms of domestic market development are ambitious, and will require a positive pricing environment if the country's needy people are to be able to access the life-saving medicines. For foreign investors, collaborations with India present a huge opportunity both in terms of joint production for the global market and supply of the growing domestic market.

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