Analysing Reverse Logistics in the Indian Pharmaceuticals Industry: A Systems Approach

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ABSTRACT *This paper analyses the complexities affecting the reverse logistics processes in the Indian pharmaceutical industry. Initial problem structuring involved the analysis of the behavior-over-time of main variables and the incorporated stakeholder analysis. Further, a participative group model building process was used to develop a systems model. In conclusion, a few strategies suggested by the stakeholders are highlighted, aimed at making long-term structural changes to the reverse logistics processes in the Indian pharmaceutical industry.*

Keywords: Reverse logistics, Systems thinking, Indian pharmaceutical industry

INTRODUCTION

The Pharmaceutical Industry in India is in a state of growth. The domestic sales are increasing continuously during the last five years and so is the number of brands. The industry is estimated to have around 23000 marketing companies and 60000 brands in the market (IMS Health 2011). Similarly, the number of manufacturers in the industry is around 10000 and growing (Department of Pharmaceuticals 2011).

[Insert Table 1 here]

The industry has been characterised by a growth with respect to revenues, number of brands and players in the market. There has also been a gradual rise in prices, as indicated by the wholesale price index for drugs and medicines. Despite this growth, the availability of essential medicines in the Indian market, especially in the public sector and rural markets has been as low as 25% (Kotwani et al. 2007). Growing incidence of product recalls, allegations of spurious drugs and issues related to expired stock in both the international and domestic markets are also a cause for concern. The seizure of large quantities of expired drugs being sold under altered labels in early 2010 raised doubts on the credibility of the industry and the regulatory control on the supply chain (The Hindu 2010). Loss due to drug expiry and product recall has also affected the sales of major players such as GlaxoSmithKline (The Hindu Business Line 2011). Quality issues are also prevalent in the supply chain, irrespective of the brand of the medicine. While the US Food and Drug Administration reports indicate an increase in the number of recalls of India-made drugs in the American market (Table 1), the same is not clearly documented on a nation-wide basis in the domestic market.

[Insert Figure 1 here]

In this context, the authors conducted some initial semi-structured interviews with distributors, retailers and manufacturing companies in the Indian pharmaceutical industry. The interviews revealed that

- The product returns percentage in the Indian pharmaceutical industry varies from 1.5% to 15% of annual sales across the companies in the domestic market. The annual estimated value of these returned medicines translates to around 5 billion Indian rupees (Table 1).

- The main reasons for the return of the products from downstream players to the companies are the expiry of the medicines, followed by issues of quality with drug composition/packaging, and the non-moving nature of the products

- The incidence of such returns has always been prevalent across all product categories.

- Products that have expired or have other quality issues are disposed through incineration or dumping, while recycling of the same is not allowed as per government regulations.

As a snapshot of the prevalent quality issues in the market, Figure 2 indicates the number of cases of Not-of-Standard-Quality (NSQ) drugs that are regularly identified by the regulatory authorities in the state of Kerala. These drugs are identified as of poor quality for reasons such as failure in tests of assay, disintegration and dissolution. Supply chain members are regularly notified by government authorities for removal of such drugs from the market as their consumption can be detrimental to the patients.

While product returns due to problems with the drugs are a common occurrence, the stakeholders who participated in the interviews were also asked about the return of good products, or effective returns, as a sustainable practice. None of the stakeholders indicated the voluntary retrieval of good products from any of the supply chain nodes unless the product had reached a status of near-expiry.

[Insert Figure 2 here]

To summarize the problem situation, though the Indian pharmaceutical market is thriving in terms of sales and the number of brands and products being produced, the incidence of unusable product returns is still present and is increasing as the market grows. Additionally, the availability of essential medicines in the public sector and rural markets is low while there is a near absence of effective returns that can be used for redistribution. So, the problem situation related to reverse logistics in the Indian pharmaceutical industry is quite complex. It is complex since there are several factors affecting this problem, and they are changing with respect to time. In this context, this study was undertaken to analyze the factors affecting reverse logistics practices in the Indian pharmaceutical industry. Given the paucity of national level data, the scope of this study was limited to the state of Kerala. This paper presents the essence of this study, including relevant literature, methodology used, data collected, and a model developed.

REVERSE LOGISTICS

The study and practice of reverse logistics in supply chain management has increasingly become a unique area of interest over the last two decades (Tibben-Lembke and Rogers 2002; Stock and Mulki 2009). A seminal review work in the field was published in the early nineties by the Council of Logistics Management (Stock 1992), while Carter and Ellram (1998) have traced indications of scientific interest in the field to the early seventies. Reverse Logistics (RL) is associated with a holistic set of activities like recycling, repair, reuse and reprocessing, as well as collection, disassembly and the processing of used products, components and/or materials (Kokkinaki, Dekker, de Coster & Pappis 2001). However, instead of a holistic approach, most journal articles on reverse logistics focus on tactical and operational problems in production planning and inventory management (Rubio, Chamorro & Miranda 2008). Also studies on reverse logistics have focused on the automobile industries, electronic goods, paper recycling, sand recycling and even carpet recycling industries, all of which display high percentages of product return and hence room for optimal and eco-efficient policies. Although there is considerable interest on environmental implications and waste minimisation concerns of the pharmaceuticals industry, reverse logistics research in this industry is limited in comparison to other industries.

Reverse Logistics in the Pharmaceutical Industry

The pharmaceutical industry refers to the complex of processes, operations and organisations involved in the discovery, development and manufacture of drugs and medications (Shah 2004). It is characterised by high investments in uncertain and long R&D activities (Talias 2007), high quality constraints and high waste to product ratios in production (Linninger, Chakraborty & Colberg 2000), long production times and shortening product cycles (Shah 2004), all of which result in high margins for sales along the pharmaceutical supply chain. The high waste to product ratios also explains the focus of research on environmental issues and waste minimisation in the production stages.

However, as most of the inventory management in the pharmaceutical supply chain is push-based up till the wholesaler level, the inventory levels tend to be very high downstream (Shah 2004). Product recovery activities downstream thus have a scope of reducing the burden on production and being economically beneficial. Increasing instances of product recalls, such as that of Vioxx by Merck and Johnson & Johnson's Tylenol, have reduced the credibility of such companies among the end consumers. An additional issue affecting the industry is that of counterfeiting, with the World Health Organization estimating counterfeit drug sales to range between $35 and 40 billion per year (8%-10% of total sales). There have been calls for proactive measures in the pharmaceutical supply chain to prevent extensive damage to the consumer/environment as well as to safeguard the brand image of the manufacturers (Ritchie, Burnes, Whittle & Hey 2000; Kumar, Dieveney & Dieveney 2009). As medicines are generally high value chemicals which are critical to the health of consumers, the proper management of product returns, expired stock and product recalls is necessary through the implementation of efficient reverse logistics systems in the pharmaceutical industry.

Studies on reverse logistics in the pharmaceutical industry have been discussed at the level of production and at the levels of distribution and sales. Teunter, Inderfurth, Minner & Kleber (2003) studied the recycling activities in the production process of a pharmaceutical company and its implications on the production planning process. At the other level are the reverse logistics activities required in managing finished product returns along the supply chain. Subsequently, product return and recovery activities have been studied for their economic implications in the distribution networks of the pharmaceutical supply chain (Ritchie et al. 2000; Amaro & Barbosa-Povoa 2008, 2009). There

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has also been an attempt at developing performance measures for the reverse logistics practices in the pharmaceutical industry (Kumar et al. 2009).

Most of these studies are case based and the applicability of the findings needs to be explored in different scenarios. Some of the major gaps in the studies are that product characteristics (e.g. expiry dates and pricing) and external factors (e.g. regulatory constraints, market behaviours, impact on consumers and environment, information systems infrastructure) have not been considered in detail. Moreover, the focus on reverse logistics activities is from a manufacturer's perspective in most cases, while in practice, the management of product returns in this industry is mostly handled by third party players or the distributors. Thus, there is a scope for studying reverse logistics activities in the pharmaceuticals industry from a holistic perspective.

In addition, research on reverse logistics has focussed on reverse logistics activities in countries like Netherlands, Germany and the USA. This has prompted researchers to expand their research to the supply chains of emerging and transition economies (Rubio et al. 2008). Therefore, this study of reverse logistics focuses on the pharmaceutical industry of India.

SYSTEMS THINKING AND MODELLING METHODOLOGY

Systems approaches were used to understand the complexities related to managing supply chains from as early as the mid 1900s (Forrester 1961). Although majority of the research focused on forward logistics activities, some reverse logistics related research was also reported. Given that reverse logistics and closed loop supply chain management involve the return of products into the supply chain, systems modelling approaches are useful for analysis and dynamic simulation of such feedback loops. Examples of the applications of system dynamic modelling include the automobile after-markets industry (e.g. Sterman 2000), paper recycling industry (e.g. Taylor 1999), electrical and electronics equipment spare parts and recycling industry (e.g. Spengler and Schröter 2003; Georgiadis and Besiou 2008), etc. There is also scope for utilising systems thinking in research efforts, which also incorporate nonmaterial elements and social aspects in reverse logistics. This allows for more qualitative and holistic research in reverse logistics.

The methodological approach of this study is based on the Systems Thinking and Modelling methodology (Maani and Cavana 2007). The two phases of this methodology used in this study follow a qualitative approach, as shown in Table 2. In the first phase, the complex problem related to product returns in the Indian pharmaceutical industry was structured systemically. For structuring the problem systemically, a behaviour-over-time chart was developed. In the second phase, a causal loop model was developed using a process called group model building. The goal of group model building is to create a consensus after sufficient deliberation of viewpoints has taken place (Vennix 1996).

[Insert Table 2]

Problem Structuring

In the problem structuring phase, a behaviour-over-time (BOT) graph was developed. Developing a 'BOT graph' or demonstrating 'reference mode behaviour' is a tool used in systems thinking to show the patterns of the main variables in a system over an extended period of time, typically several months to several years. Such patterns can indicate the variations and trends in the variable of interest, for example, growth, decline, oscillations, or a combination thereof. The important elements captured by a BOT graph are the overall trends, directions and variations, not the numerical value of the variable. Therefore, BOT graphs are usually drawn in a rough sense without exact numerical values attached (Maani and Cavana 2007).

[Insert Figure 3 here]

In this study, a BOT chart (Figure 3) was drawn to capture the trends of six variables including domestic sales, number of brands, price represented by WPI, estimated product returns, number of NSQ cases and effective returns. These trends are based on data from Tables 1, Figure 1, Figure 2 as well as interactions with the stakeholders in the pharmaceutical industry. In this BOT graph, the industry shows an increase in sales and number of brands in the market. This positive outlook of the industry is accompanied by a slow but gradual increase in the prices of medicines as well, indicating that medicines are getting costlier for the consumer. At the same time, there seems to be an increase in presence of products of poor quality in the market and an increase in the value of products that are returning from the market. However, the BOT graph shows that the voluntary retrieval of good products from the market or effective returns is quite low.

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GROUP MODEL BUILDING

In the second phase of this study, a group model building exercise was conducted to develop a causal loop model. For this purpose, ten key stakeholders, belonging to the different categories, as identified in the stakeholder map were brought together to participate in the group model building exercise. In this qualitative group model building approach, hexagons are used for systems thinking, based on Hodgson's (1994) use of hexagons for issue conceptualisation and Kreutzer's FASTbreakTM process (1995) for using hexagons to develop causal loop diagrams. In this qualitative group model building approach, the following four steps were used:

Hexagon generation; Cluster formation; Variable identification and Causal loop development

Step 1: Hexagon Generation: This step consisted of generating hexagons for each issue, opportunity or obstacle identified by the stakeholders. To help the stakeholders in generating hexagons, an organising question was used. The organising question was 'What are the factors that affect the product returns in Indian pharmaceutical industry?' During this step, hexagons were used as a facilitation tool. One of the authors acted as a facilitator and recorded issues, opportunities or obstacles identified by the participants. The stakeholders who attended this session generated 38 hexagons.

Step 2: Cluster Formation: In this, hexagons that have something in common were identified by the stakeholders. They grouped such hexagons together to form clusters. Then a descriptive name was given to each cluster. In this step, the stakeholders made 7 such clusters. The descriptive names given to each of these 7 clusters include business value for manufacturing, reduction of all stakeholder risks, ethical medical practice, customer awareness and benefits, third party involvement, and new policy initiatives.

[Insert Figure 5 here]

Step 3: Variable Identification: In this step, the stakeholders identified a few variables associated with each cluster. Overall, thirty variables were identified (Table 3).

[Insert Table 3 here]

Step 4: Causal Loop Development: During this step stakeholders tried to establish possible links between variables. First they identified any two variables that were related and provided a

directed arrow between them. To generate a directed arrow, they placed a positive (+) sign near the head of the arrow if an increase (or decrease) in a variable at the tail of an arrow caused a corresponding increase (or decrease) in a variable at the head of the arrow. If an increase in the causal variable caused a decrease in the affected variable, a negative (-) sign was placed near the head of the arrow. At the end of the group model building exercise, a general agreement that this model represented their shared view was obtained from the stakeholders who participated in this meeting. The analysis of the model is currently out of the scope of this paper.

FINDINGS & CONCLUSIONS

After the group model-building exercise, the stakeholders identified a few plausible initiatives to address the problem, aided by insights from the causal model. The interacting variables in the causal model depicted three inter-related areas of concern, namely, market flooding, weak infrastructure for performance and quality management and inefficient systems. These areas of concern explain the current trends in the pharmaceutical industry and pose a threat to the management of the reverse logistics activities.

The continued presence of expired and poor quality drugs was attributed to the market flooding of "me-too" drugs, which are unnecessary in the market. Poor marketing and management of these excess drugs in the supply chain has resulted in the presence of disposable (expired and damaged) medicines that are continuously returned to the companies. The flooding has also been attributed to a stringent but low-coverage pricing policy that encourages players to produce several other unnecessary drugs that are not under price control (Sakthivel and Nabar 2010). Improvement in the pricing and regulatory policies, increasing consumer awareness on medicine usage and the pooled procurement of medicines were recognized as measures that can improve competition and quality among players and alleviate market flooding.

Secondly, it was identified that the present infrastructure for performance and quality management in the pharmaceutical supply chain is weak and enables the continued presence of expired stock and poor quality medicines in the market. Subsequently, the stakeholders suggested the need for (i) increasing awareness among supply chain members with respect to quality policies, (ii) improving product tracking by implementing technological advancements, (iii) increasing the

visibility of poor quality and expired stock by publishing details of such drugs at a national level and (iv) assessing and revamping current government regulations and resources with respect to managing product quality in the industry.

Among inefficiencies in the system, it was identified that procedural delays in reimbursement discourage timely return of products and hence, led to more market flooding. Low acceptance of good product returns in the supply chain was attributed to the cost-intensive nature of reverse logistics that discourages investment in effective returns as a sustainable strategy. In this regard, there is a need to explore a cost-benefit analysis of effective returns process, risk-sharing among supply chain players, reduction of delays in the system such as reimbursement delays and the involvement of third party players in handling product returns. Such initiatives call for redesign of the reverse logistics processes at a system-wide level.

By analysing complex interaction between factors that affect the reverse logistics processes, this study lays a platform for building a system dynamics simulation model, capable of evaluating different strategic options for improving reverse logistics processes in the Indian pharmaceutical industry. Additionally, the study opens up avenues for future empirical studies in reverse logistics and the related problem areas.

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TABLES

Table 1: Data for Indian pharmaceutical industry (2006-2010)

Year	2006-2007	2007-2008	2008-2009	2009-2010	2010-2011
Total Domestic Market Value (Rs. Billion)[a]	374.1	417.8	496.6	590.2	690.5
Minimum estimated value of returned medicines (Rs. Billion)[b]	5.61	6.27	7.45	8.85	10.36
Number of FDA Recalls of India-made drugs in the U.S. Market[c]	0	2	2	5	20
Wholesale Price Index (Annual; Base Year 2004-2005 = 100)[d]	102.56	108.11	111.41	112.72	114.5
Domestic Sales of select players (Rs. Billion)[e]	279.58	321.62	354.75	418.23	482.39
Number of brands of select players [e]	23056	23966	24603	26279	27446
Number of select players [e]	440	453	450	456	453

[a]Source: Datamonitor (2010); [b]Estimated at 1.5% of Domestic Market Value; [c] Source: Collated from U.S. Food & Drug Administration (USFDA) drug recall alerts maintained at http://www.fda.gov/Safety/Recalls/default.htm; [d]Source: OEA to the Government of India Ministry of Commerce and Industry; [e]Source: Data obtained from a leading multinational pharmaceutical company with access to market intelligence provided by IMS Health.

Table 2: Methodological Framework

Phases	Steps
Problem Structuring	Behaviour over time chart development
	Stakeholder analysis
Causal Loop Modelling (using Group Model Building)	Hexagon generation
	Cluster formation
	Variable identification and
	Causal loop model development
	Causal loop model analysis

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Table 3: Variables identified in the group model building session

Variables	
1. Sales	16. Material handling & transport costs
2. Return of disposable products	17. Marketing
3. Reimbursement claimed	18. Market flooding
4. Reimbursement	19. Incentives to sell price leader
5. Regulatory pressures	20. Incentive to return disposable products
6. Production	21. Incentive to make effective returns
7. Price	22. Effective returns
8. Number of unsold drugs in market	23. Supply of effective returns
9. Number of poor quality drugs	24. Demand- Supply gap
10. Number of players	25. Demand
11. Number of "Not of Standard Quality" drugs (NSQs)	26. Damage to company image
12. Number of non-moving drugs	27. Company's refusal of effective returns
13. Number of expired drugs	28. Company's pressure to liquidate stock
14. Number of disposable products	29. Attractiveness of market
15. Number of brands	30. Sales of other brands

FIGURES

Figure 1: MonthlyWholesale Price Index for Drugs & Medicines (Source: OEA to the Government of

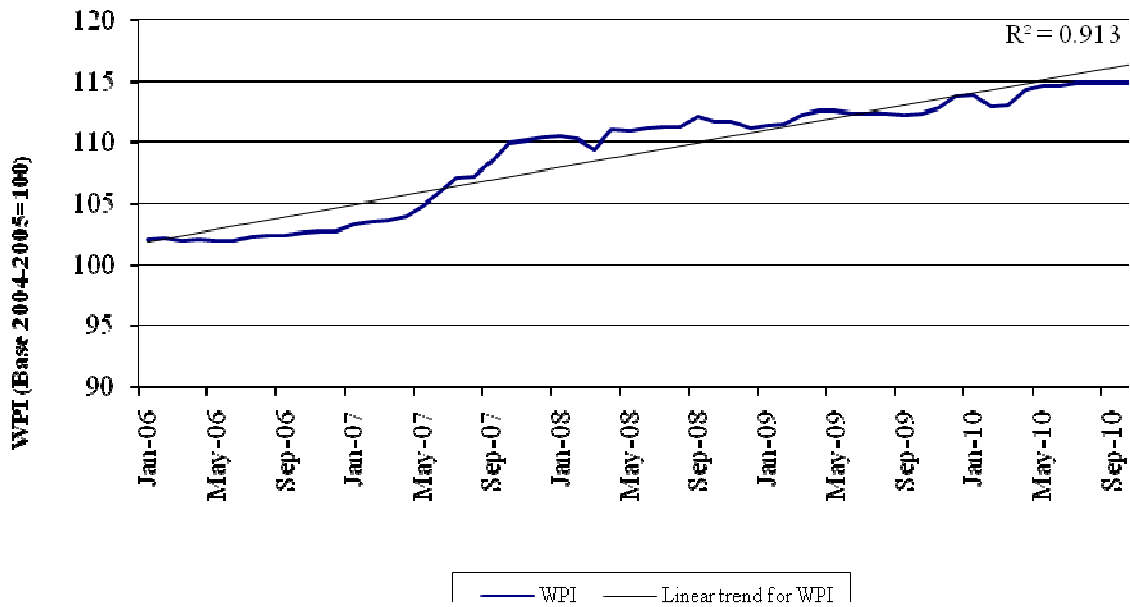India Ministry of Commerce and Industry)

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Figure 2: Trend of "Not-of-Standard-Quality" cases of medicines in the market identified by government inspection in Kerala, India (Source: Collated from NSQ reports maintained at http://dc.kerala.gov.in/index.php/alerts/70-substanddrugs.html)
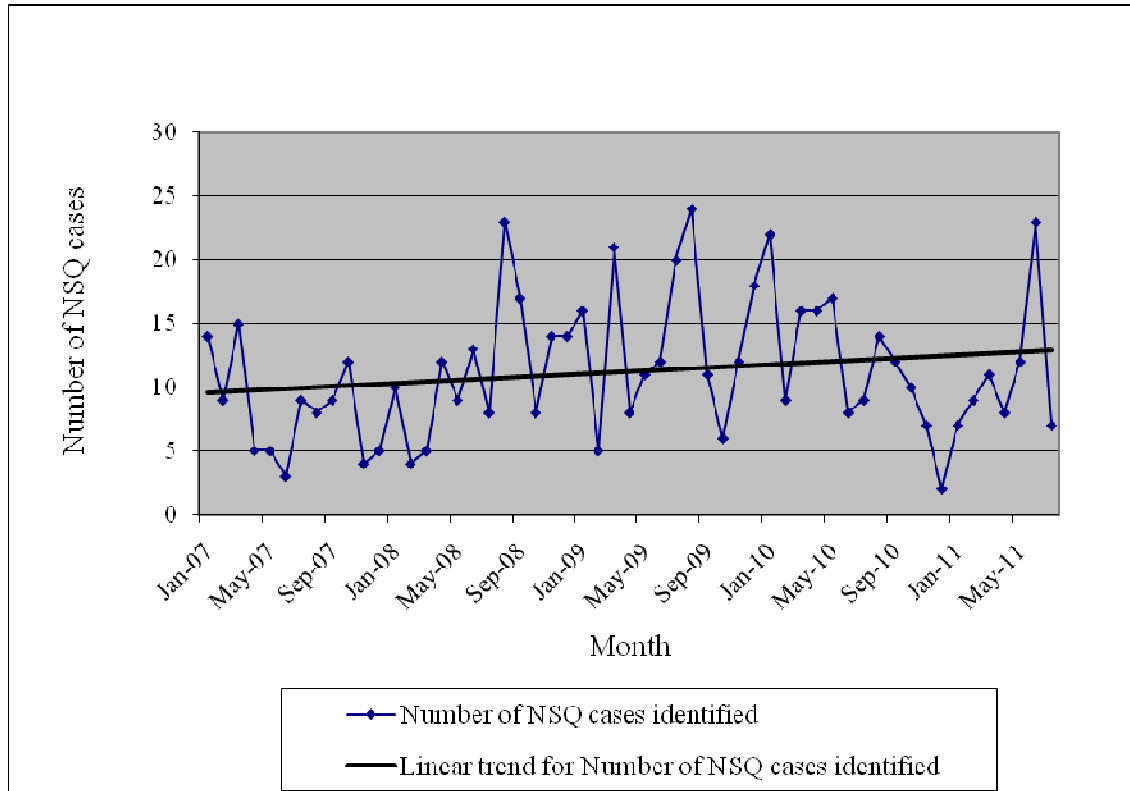
Figure 3 Behaviour-over-time (BOT) graph

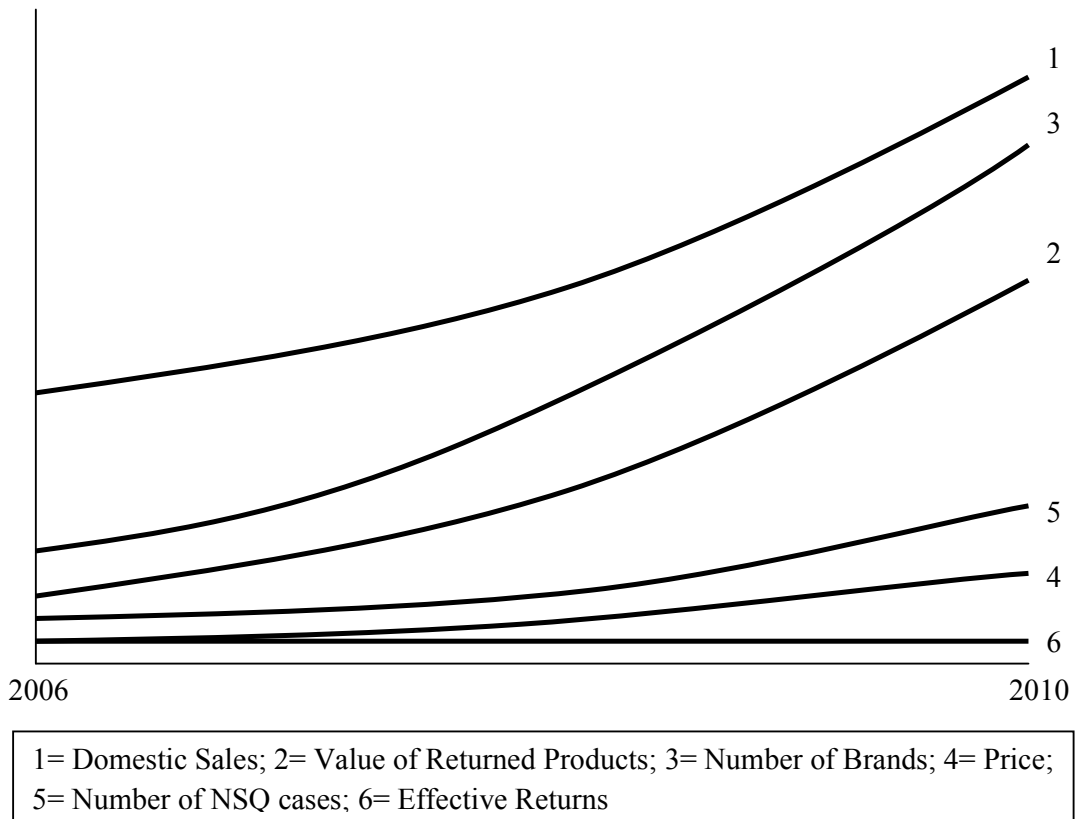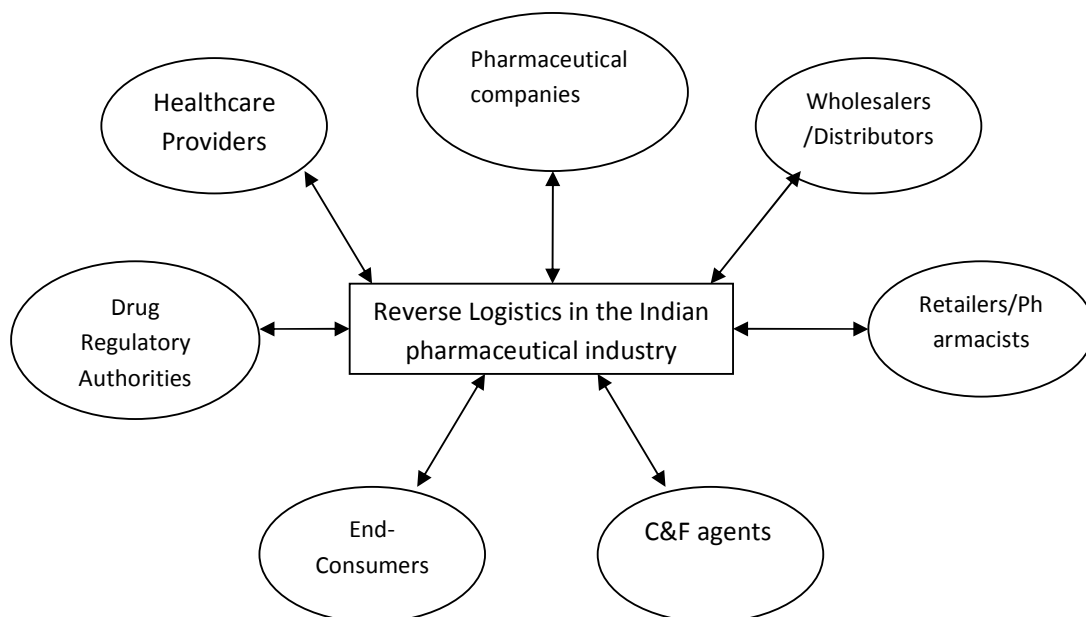| 1= Domestic Sales; 2= Value of Returned Products; 3= Number of Brands; 4= Price; 5= Number of NSQ cases; 6= Effective Returns |

Figure 4 Stakeholder Map

Figure 5 Example of a Cluster – 'Reduction of all stakeholder risks'