White Paper on

Pharmaceutical Supply Chain Challenges & Best Practices

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Introduction

The Pharmaceutical Supply Chain is very complex and highly responsible to ensure that the right drug, reaches the right people at the right time and in the right condition to fight against disease and sufferings. This is a highly sensitive supply chain where anything less than 100% customer service level is unacceptable as it directly impacts the health and safety. The solution that many Pharmaceutical industries adopt is to carry a huge inventory in the supply chain to ensure close to 100 percent fill rate. However, it is a big battle to ensure 100 percent product availability at an optimal cost unless supply chain processes are streamlined towards customer needs and demands.

The time to Market, R & D productivity (Innovations), Product Life cycle shrinkage, Government Regulations, shortening exclusive Patent life, Production Flexibility, and Increasing Cost are the key challenges that pharmaceutical industries are facing today. A manufacturer who can trim development time by 19% can save up to $100 million (source: Sangita viswanathan, 2004). When a drug getting delayed to reach the market costs companies around $1 million a day, the time to market is extremely critical for pharmaceutical companies in order to introduce a drug as soon as possible.

The Indian pharmaceutical Industry with a worth of US $4.97 billion in 2002, is entering a new era in 2005, where the product patent would come into effect and it would imply radical changes in the value chain. India with high quality and productivity rates (more than 60 Indian manufacturing facilities are approved by FDA, India is only next to USA in terms of number of plants approved by FDA), huge talented scientists pool, low cost, and large patient population, has a huge

opportunity to tap the world outsourcing market, which is estimated at $ 53.2bn in 2003 and growing at CAGR 10.8%. In this context, this white paper attempts to explain the pharmaceutical supply chain challenges and best practices required to sustain a competitive edge in the market by meeting customer needs and demands at right time.

Market Overview

Global Market

The world pharmaceutical industry grew by 8 % year on year to $ 541.0 billion in 2002, driven primarily by the demographic shifts (i.e. increasing elderly population), changing epidemiological patterns, increase in healthcare awareness and the ability of the industry to provide innovative cures for various ailments. The world's per-capita spending on pharmaceuticals has increased steadily from $72 in 2000 to $87.1 in 2002. Among the four major areas in pharmaceutical viz. ethical, generic, OTC and biopharmaceutical, ethical pharmaceuticals account for 74 % of the total market share with a double-digit growth rate. However it has been facing a stiff competition from generic market, which was valued at $30.5 billion with a 6% share of total market and biopharmaceutical sector, which valued at $31 billion. (Source: BCC, Inc., IMS health).

The pharmaceutical industry has been in the phase of consolidation for the last few years as the top 10 companies share has been increased from 28% in 1990 to 46% in 2002 due to major acquisition and mergers during this period. North America is the biggest market for pharmaceuticals with a share of more than 50% followed by Europe and Japan with a share of 22 % and 12 % respectively.

Worldwide Pharmaceuticals Market by Sectors, through 2008 ($ Billions)

	2000	2001	2002	2003	2008	AAGR% 2003-2008
Ethical	317.1	363.4	401.0	437.6	677.8	9.1
Generics	24.0	27.0	30.5	37.0	64.0	11.6
OTC	70.5	73.8	78.5	82.0	101.0	4.3
Biopharmaceuticals	22.1	26.3	31.0	36.5	58.6	9.9
Total World Market	433.7	490.5	541.0	593.1	901.4	8.7

Source: BCC, Inc., IMS Health

Table 1

Indian Market

The Indian pharmaceutical industry is one the of fastest growing sectors in India, and satisfies more than 95 % of domestic market needs. This Industry in India is growing at a CAGR 19.8 and reached US $4.97 billion in 2002 and it is projected to touch US $45 billion. The top 30 players control about 70% of the market share.

The total Indian production constitutes about 1.3% of the world market in value terms and 8% in volume terms, and India ranks globally 4th in volume term and 13th in value. More than 60 Indian manufacturing facilities are approved by some of the high standard regulatory agencies such as US FDA, UK MCA, Australian TGA, and WHO etc. And the number of Drug Master Files (DMFs) filed in 2003 with U.S FDA is 126, which is higher than the number filed by Spain, Italy, China and Israel. Complex synthesis capabilities, increasingly good manufacturing practices (GMP) and low-cost production are the core competencies of Indian Industry. However, increasing generic penetration, intense competition and fragmentation of the industry are the key challenges that Indian pharmaceutical industry faces today. (Source: www.indiaoppi.com).

Pharmaceutical Supply Chain

Why supply chain excellences in Pharma

The Pharmaceutical Supply Chain is very complex and highly responsible to ensure the right drug, at the right time, at the right condition, to the right people worldwide to fight against disease and sufferings. For example, at one large global pharmaceutical company, over 40, 000 stock keeping units are distributed worldwide, which in some cases includes some very specialized products. To reach the final customer different channels are available viz. wholesalers, retailers, doctors or other channels. It is really a great challenge for a company to reduce finished goods inventory, as 40,000 SKUs have to go through a complex network - multiple plants and warehouses create over 10, 000 nodes, before reaching the final customer.

Pharma Supply Chain

Pharmaceutical Supply Chain

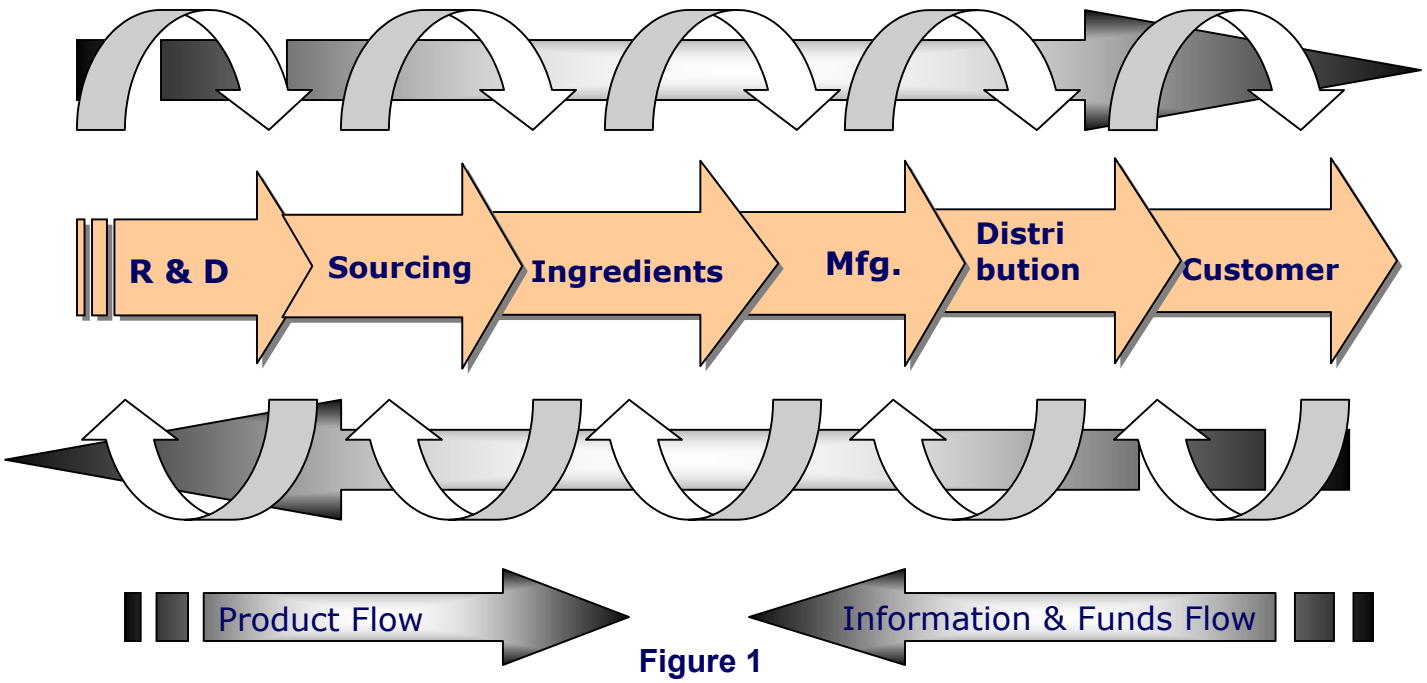

Figure 1

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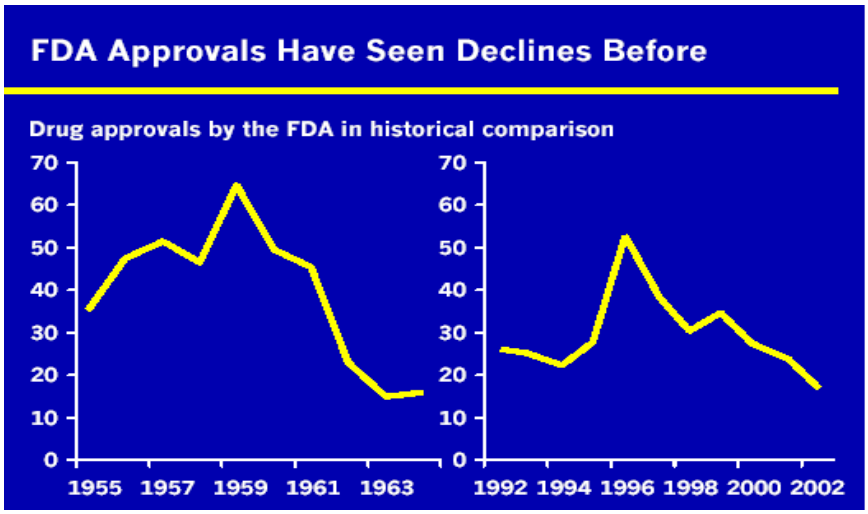
The pharmaceutical supply chain like in other industries starts with the sourcing of active and inactive ingredients for approved products. Dosages[1] are formulated and packed into various configurations. Products flow through company warehouses, wholesale distributors, retail pharmacies, medical institutions, and finally to consumers. The information flow and funds flow start from customer end to Producer end through various channels

Supply Chain Challenges in Pharma – Time Matters

The time to market is critical in Pharmaceutical Industry as the product patent exclusivity periods have shortened, which puts a lot of pressure on pharmaceutical industry, about 24 drugs with annual sales over US$ 500 million will go off-patent in the first half of this decade (2000-2005). According to an estimate, it costs a company about US$ 800 million to get a drug from the laboratory to the patients in the US. A manufacturer who can trim development time by 19% can save up to $100 million. When a drug getting delayed to reach the market costs companies around $1 million a day, so the time to market is critical for pharmaceutical companies in order to introduce a drug as soon as possible to the market by reducing the time lost in the development processes.

The cost of R & D has been increasing while the R & D productivity has been declining. In US, FDA approved only 17 NCEs in 2002 when compared to 56 NCEs approvals in 1996, though the companies have doubled their R & D expenses between the same periods. The average cost of developing a drug is growing at a compounded annual rate of 7.3% from $ 138 million in 1975 to $318 million in 1987 million in 2003, according to a Tufts Center for the study of drug development report.

[1] Dosages-consist of different forms for the same active ingredient such as tablets, capsules, injectables etc. Further, with international marketing focus, packs and pack inserts are to be made in different languages and meet with the regulatory requirements of the respective countries.



Source: FDA, Credit Source: FDA,
Credit Suisse/First Boston
Suisse/First Boston

Supply Chain Costs in Pharma

The pharmaceutical supply chain like any other industry has a challenge to streamline the flow of products, information and funds from R & D stage to sourcing to ingredients and manufacturing to distribution to final customers. What makes Pharmaceutical supply chain is so different from others is that social responsibility that pharmaceutical industry has got to ensure 100 % product availability at the right time, at the right cost, in good condition (counterfeit issues) to right customers.

In order to ensure close to 100% product availability, many industries have taken the strategy of keeping a huge inventory in their supply chain as pharmaceutical products margin is remarkably high but the lifespan of patents is limited. So there is no wonder why logistics cost shares 45 to 55% among other costs in the pharmaceutical value chain, as pharmaceutical industries are willing to keep supply at any cost.

The Value Chain Cost Distribution

Value Chain Stages	Cost Distribution
Research & Development Cost	15%
Primary Manufacturing cost	5 – 10%
Secondary Mfg/Packaging	15 – 20 %
Marketing / distribution	30 – 35%
General Administration	5%
Profit	20%
Total	**100 %**

Source: Imperial College London

Table 2

[2]Survey report on Performance measures in Pharma Supply Chain

- Pipeline stocks may be 30 -110% of annual demand
- Finished goods stock 10 - 50% (4-26 weeks) of annual demand
- Supply chain cycle time of order 1000s of hours
- Value added time 0.3 - 5% of cycle times
- Supply chain costs overtaking R&D costs

[2] Source: Imperial College London

The above-mentioned report shows that the pharmaceutical industry has got a huge potential to trap supply chain cost in the value chain as supply chain costs more than R&D costs. Hence company should map their supply chain process and optimize the same to ensure the product availability at optimal costs. Optimizing supply chain would result in 30% stock reduction, 30% increase in value – added time and 7% reduction in supply chain costs, which has been proved by one large drug maker, who reduced supply chain costs up to $30 million with $ 8-16 million p.a.

Counterfeit Issues in Pharma Supply Chain

The treat of counterfeit drugs entering the marketplace is greater than ever before and so is the risk of pilferage. A recent report in wall street Journal noted that, in several scams, drug companies have had drugs enter the supply chain because new theology make it easy to forget prescription drug labeling and because the high price of drugs in the US has fuelled demand for inexpensive suppliers. For example, Pfizer had a case where its cholesterol drug Lipitor recalled as many as 200, 000 bottles which had a total market value of about US$ 55 million, containing fake pills from outside the US.

The number of cases of counterfeiting reported by the FDA has risen from four in 1998 to over 22 in 2002. It clearly emphases the complexity of supply chain design for today environment. Hence, the Supply chain managers should rethink their strategy and process on distribution, warehousing, transportation, and outsourcing activities in order prevent counterfeit in their supply chain. The new technologies such as Radio Frequency Identification (RFID) would help to track and trace the products and prevent any counterfeit activities into the products from the designing stage to consumer stage.

Best Practices for Pharma Supply Chain Excellences

The speed, flexibility, visibility, Responsiveness, costs and safety are the key drivers for the pharmaceutical supply chain excellences. The collaborating planning and forecasting with supply chain partners (contract manufactures and 3rd party service providers), Outsourcing, earlier involvement of vendor in product designing, technology integration and continuous improvements through supply chain metrics are the key strategies for the pharmaceutical supply chain to ensure the product availability at optimal costs in today environment.

Outsourcing – Speed, Flexibility and Responsiveness

Outsourcing is the key strategy to reduce time to market and increase the flexibility. Today pharmaceutical Industry is moving toward planning for a range of capabilities instead of for specific product requirements. An outsourcing partner who can reduce product development cycles, eliminate bottle – necks and provide immediate access to advanced technologies and expertise would be a valuable assets. Such flexibility would also ensure the responsiveness by responding to customer requests for special packaging or labeling, quickly adopting new production technologies, or getting new products on the market as soon as they receive approval. The time required to establish new capacity is significant: 3 –4 years for bulk production and 2-3 years for formulation. Hence company should use outsourcing as a key strategy for competitive advantage rather than reducing companies burden on non-core activities. Companies should also leverage the clinical research outsourcing potential in order to gain the competitive advantage by reducing product development time.

India has a huge opportunity to trap the world outsourcing market, which is estimated at $ 53.2bn in 2003 and growing at CAGR 10.8%. India has the key

ingredients, technical skills, and regulatory compliance, cost advantage and global relationships to emerge a powerhouse in this sector. According to Kotak Report, the bulk outsourcing or manufacturing outsourcing currently at $14 billion and slated to grow to $27 billion by 2007(Source: www.pharmaquality.com). It is a segment where Indian companies can best exploit. With India being favorably looked upon by the top pharma companies of the world, the need to match and meet world standards in supply chain is more critical than ever before.

Technology Integration – Visibility

Though the security of data appears to be sacrosanct, companies should share necessary data with at least key vendors and customers in order to avoid any lost sales, missed deliveries, obsolete inventory, and poorly planned promotions. Sharing the information with vendors and early involvement of them into product designing would cut the development process time. Though forecasting accuracy has been shown to improve from 30% to 65% over a 12 week forecast in the Pharma industry, there is lots of scope to improve it further. For instance, recent research suggest that the first seven weeks of new product demand data is enough to establish a trend for planning if the companies integrate their vendors and customers along the supply chain by sharing the information at right time by implementing tools like Collaborating Planning, Forecasting and Replenishment (CPFR) and Vendor Managed Inventory. Hence pharmaceutical players should rethink their strategy on information sharing in order to sense the real demand in the market.

Metrics – Continuous improvements

To ensure the continuous improvements in supply chain processes, the pharmaceutical company needs to put in place clear performance measures. What gets measured gets noticed and improved continuously. The best approach is to assemble a performance scorecard of metrics that are key to the

business, and the metrics should be objective, quantifiable and balanced. The SCOR (Supply Chain Operations References) Model and Balanced Score card are the some famous performance measurement models. Responsiveness, Flexibility, Inventory turn over, Cash to Cash Cycle and Asset Turn over are the some key performance indicators in Supply Chain.

Conclusion

The pharmaceutical has got a tremendous opportunity to lower costs, improve asset management and enhance customer service by implementing supply chain best practices such as CPFR, Outsourcing, VMI and Lean thinkings. The companies that adopt these practices will gain a competitive advantage over their rivals, and costs and speed of response will be orders of magnitude lower than traditional methods.

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