Pharmaceutical Supply Chains: Risks, Challenges and Strategic Response

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A pharmaceutical supply chain consists of sourcing of ingredients and technology, production, distribution and delivery mechanisms to provide medicines and supplies to patients and healthcare facilities in a cost effective and timely manner. This paper introduces the structure of pharmaceutical supply chains within the larger context of health care supply chains and provides discussion on past work and the emerging trends in pharmaceutical supply chains. The paper further explores the unique operational challenges and strategic issues faced by the pharmaceutical supply chains. The paper further proposes a strategic response framework and a mapping tool to deal with these risks and challenges.

Keywords: pharmaceutical supply chain, strategic response, strategic mapping, risk management

INTRODUCTION

Pharmaceutical supply chain (PSC) involves the processes of sourcing, manufacturing, distributing and delivering drugs and pharmaceutical supplies to the retailers, hospitals and end-users of these products. This supply chain aims to provide the medicines in the right quantity, to the right place, at the right time and at an affordable cost while maximizing the financial benefits for its shareholders and meeting the regulatory requirements of the health care system. This is achieved through a complex network comprising of various business and non-business entities such as drug manufacturers, distributors, research organizations, laboratories, government agencies, regulatory authorities, retail pharmacies, and healthcare facilities. Several regulatory mechanisms and checks and balances exist in this supply chain network to ensure a safe and effective supply. Besides the retail segment, the diagnostic, treatment and prevention products are also an important part of the PSC.

The larger multinational companies dominate the pharmaceutical landscape due to their global outreach and resource access. This dominance poses certain risks to the healthcare system due to lack of abundant supply during pandemic times, supply disruptions, lack of contingency planning and quality issues. The competitive landscape in the pharmaceutical industry is changing, bringing newer possibilities, opportunities, challenges and consequences. Under this dynamic environment, pharmaceutical companies must stay ahead and proactively devise sound and robust strategies to ensure sustainable profits. These strategies typically revolve around revenue management principles, product promotion, price adjustments and developing R&D capabilities to create newer and more profitable product lines. The stronger emphasis on R&D efforts helps in treating previously untreatable medical conditions and results in newer products, services and revenue streams for the PSC. However, harvesting R&D benefits is often short-lived because the innovative firms start facing stiff competition from generic drug companies, alternate treatments and drug counterfeiting. Therefore, these innovative companies are always exploring newer strategies and

product offerings. The price sensitivity of the market and the shift in payment responsibilities between patients, insurance providers and the Governments presents a highly dynamic client base to PSCs. In this era of globalization, medical tourism, virtual treatments, and mail-order pharmacies, the front end of these supply chains is complex.

Healthcare industry faces more stringent laws and regulatory guidelines from the Governments and watch dog organizations compared with consumer goods industries, which hinders the innovation potential of health care industry. The life cycle of drugs is shortening due to safety and product expiry concerns (Clauson et. al 2018). Although the role of regulatory processes cannot be over-emphasized and these control mechanisms are necessary to ensure a safe use of pharmaceutical products, these regulatory processes are often slow and have negative outcomes for the pharmaceutical industry.

The manufacturing channels of this industry comprise a network of research, technology transfer and drug production companies and laboratories. These organizations require a highly skilled, trained and educated workforce compared to other industries. Towards the upstream of this supply chain, the pharmaceutical firms comprising the supply chain are highly involved in the design and development phase of their products such as supplying ingredients for the drug, subsequent clinical trials, testing and meeting the approval requirements. Towards the downstream, these supply chains have a higher degree of involvement in the sales and distribution functionality as compared with other industries. Therefore, the pharmaceutical companies are more vertically integrated than their consumer goods counterparts. Pharmaceutical supply chains are mostly responsive supply chains rather than efficient supply chains. The expectations in terms of innovation, initiatives, agility, speed, product availability, and safety requirements are the major factors that make them responsive supply chains. Due to this increased emphasis on responsiveness rather than operational efficiency, pharmaceutical product costs have been ever increasing. The issue of medicine cost is important to both patients and hospitals. Studies suggest that the maximum reimbursed amount in several cases even falls short of the cost of a medicine (Franco 2020).

During PSCs' pre-approval and post-approval stages, the major drivers, objectives and constraints experience a significant shift. From the ability to recognize future market trends and the agility to produce and deliver newer drugs, the emphasis shifts quickly to ensuring peak product availability. Examples of these challenges can be found during tough pandemic times such as COVID-19 where the developed and approved vaccines are manufactured, distributed and administered to the public at a massive scale and in a record time. This throws the production and distribution functions into top gear. The shift in priorities from shrinking the product development cycle to gain a first mover advantage in the marketplace to increasing the product's life cycle for recovering R&D expenses and harvesting the economic gains presents some unique challenges for these supply chains. For example, the shift in priorities results in a shift in the models, techniques and principles on which the supply chain processes need to operate and respond. As a result, many companies end up merely managing these supply chain networks rather than achieving a high degree of operational excellence.

TRENDS & LITERATURE REVIEW

The findings from past studies on PSC have revealed some interesting facts, but the literature on PSC is generally still scarce. Past work is categorized under the sub-areas of resources, processes and performance measurements (Narayana et. al 2014; Singh et. al 2016). It is conjectured that forces such as compensation influence, power dynamics, regulatory constraints and the role of intermediaries may radically change the structure of PSC with far reaching effects on the product pedigree and proliferation in this industry (Rossetti et. al 2011). The impacts of defective product recall, production disruptions, decentralization and selling prices on the PSC performance have been investigated (Hosseini-Motlagh et. al 2023). Some of the important dimensions for creating value for end-users, patients and health care providers are identified as availability, access, affordability and safety of the drugs and this list is not exhaustive by any means (Narayana et. al 2014; Pitta & Laric 2004; Sinha & Kohnke 2010).

Strategic approaches based on decision support tools such as optimization and simulation can help to develop healthcare policies. Inventory policies based on variable lead times, payment delays, space

constraints and the optimal customer service level have been attempted in the past work (Uthayakumar & Priyan 2013). Demand forecasting is a pre-requisite to an effective inventory management policy and hence it can play a vital role in managing pharmacare supply chains. Integrated planning based on intelligent forecasting models and purchase order generation is essential to smoothly run these supply chains in health care field (Galina et. al 2019). Operations management techniques have been applied to assess the potential risks in PSCs. For example, it is concluded that the risks such as import fluctuation, lack of information, supplier failures and non-availability of raw materials have priority over operational, financial and demand-related risks (Moktadir et. al 2018). The carbon footprint assessment of these supply chains and incorporating green ideas into PSCs has also been an area of interest for some academic researchers and practitioners. It is shown that the cold chain technology and supply related rank higher as potential risks for adopting green principles in PSC (Kumar et. al 2019).

Various aspects of network design, logistics and distribution planning such as transportation modes, fleet sizing, locational planning and uncertain demand have been explored in the literature (Aura et. al 2022). Literature surveys on implementing block chain technology in PSCs is available in Fernando et. al (2019) and De-Aguiar et. al (2020). A Blockchain and Internet of Things (IoT) based tracking and tracing system for pharmaceutical supply chain is introduced in Liu et. al (2021). According to Ilgar (2024), visibility and collaboration are the key strategies to anticipate potential shortages, manage active ingredient stock levels, and enable the pharmaceutical industry to detect the disruptions early on. Abas et. al (2020) proposed blockchain and machine learning-based models for drug recommendations in pharmaceutical supply chain. Samantray & Reddy (2025) introduce a novel blockchain-enabled healthcare supply chain management model for real-time tracking and secure management of healthcare products and transactions.

Pharmaceutical industry and its allied service and manufacturing organizations are experiencing a marked shift in the trends. The focus is moving from a diversified market to a standard one. These trends, triggered by competition and some internal factors, are expected to affect the processes in coherent and interdependent pharmaceutical supply chains. Besides the efficacy of existing products to deal with future challenges, the frameworks for ensuring a close working relationship between the drug approval authorities, Governments, pharmacare companies and healthcare providers are expected to be a part of the future research agendas. The major players in the industry such as brokers, insurance providers, healthcare administrators and the patients are becoming increasingly more cost-conscious. The involvement of various stakeholders in cost cutting measures, leveraging existing government and non-government networks, and the urgency to address the healthcare challenges will give rise to newer supply chain models. The R&D budgets in the healthcare supply chain sectors are likely to experience growth (Kumar & Jha 2019). Further developments in the cost control arena are likely to be outsourcing, centralized warehousing, direct shipments and an emphasis on the applications of total quality management in this industry (Sriyakul & Jermsittiparsert 2019). Other emerging trends are the ability to utilize various production and distribution modes to handle the diversified pharmaceutical products and their packaging requirements (Esmaeillou et. al 2017). Further emerging trends in the industry will be related to the generic product market expansion because customized and branded drugs are focused on a narrow range of customers (Burinskiene 2018).

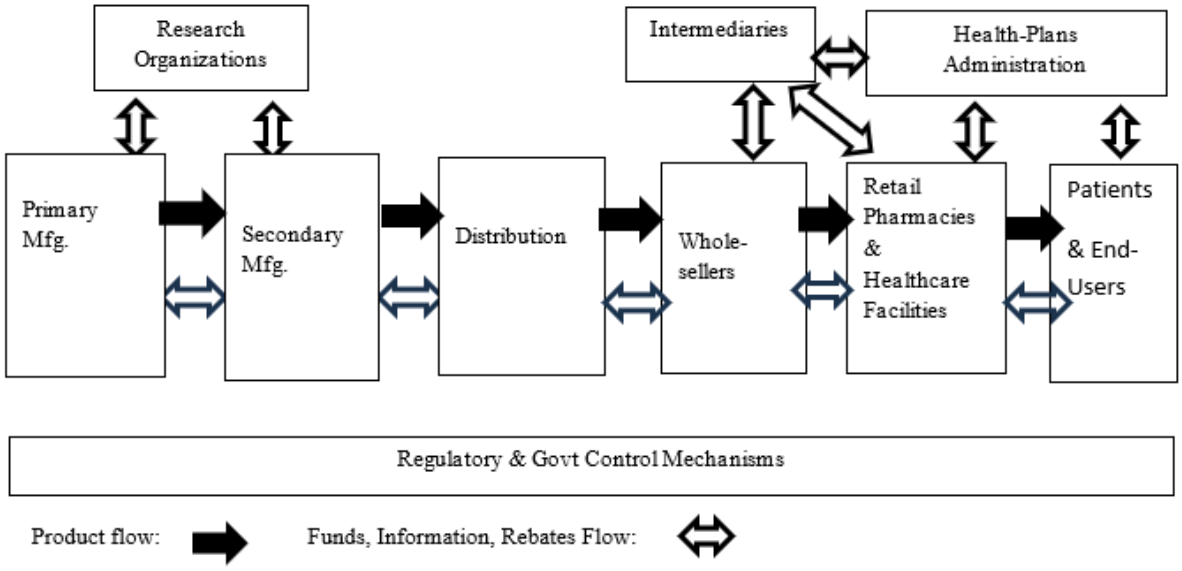
PHARMACEUTICAL SUPPLY CHAIN STRUCTURE

The diversification in PSCs, the possibility of vertical and horizontal integration and different business models give rise to highly complex PSCs. Therefore, a variation from the provided generic supply chain structure is expected. The main players in PSC include clinics, hospitals, drug manufacturers, pharmacy chains, Government and regulatory bodies such as the Foods and Drug Administration (FDA), research organizations, labs, retailers, government agencies, insurance companies, intermediaries, distributors, whole-sellers, and in some cases- even the medical tourism companies. Below in Figure 1, we outline the structure of a PSC in a generic sense. However, as indicated above, additional stages and players may be noticed in supply chains specific to different geographic regions and business contexts. The main players in this supply chain are:

- Manufacturing (primary and secondary)

- Distribution (storage and transportation)
- Wholesalers
- Intermediaries
- Healthcare plan administrators & insurance providers
- Healthcare facilities (hospitals, clinics) and retail pharmacies

FIGURE 1
GENERIC STRUCTURE OF PHARMACEUTICAL SUPPLY CHAIN



Manufacturing

The manufacturing stage is an initial stage of the PSCs, and it consists of primary and secondary manufacturing.

Primary Manufacturing

The primary manufacturing function produces the active ingredients called API (Active Pharmaceutical Ingredient). This step synthesizes chemicals, develops complexity, fermentation, and purification of the chemical processes. The various operational steps in primary manufacturing need to go through very tight quality control checks. The major challenges at this stage are the outsourcing of API's, coordination between manufacturer and sub-contractors and research labs, and the skilled labor shortage in terms of scientists and engineers who can ensure quality.

Secondary Manufacturing

Secondary manufacturing takes the active ingredients as raw material inputs to the system, adds subsequent ingredients, completes final assembly and mixing steps and creates a market sellable product. Examples of this stage include making pills, injections, capsules or other product forms.

Distribution

Besides the lead-time challenges in PSCs, the other issues in this sector are providing safe storage and product movement at affordable costs. Distribution function ensures product availability by delivering the right products to the right locations in a timely manner. The challenge was obvious during the COVID-19 vaccine distribution where large quantities of vaccines were required across the globe at affordable costs.

Wholesalers

Wholesalers have an important role to play in pharmaceutical supply chains. To achieve economies of scale, there are fewer but larger wholesalers in the pharmaceutical sector. Since the secondary manufacturing sites are geographically diverse and follow decentralized strategies, this leads to transportation and distribution inefficiencies and longer lead times. The strategic response to address this issue is to introduce a wholesale stage in the PSCs.

Intermediaries

Intermediaries are third-party stakeholders between wholesalers, retail pharmacies, and health care facilities. In some countries, they are also known as pharmacy benefit managers. Their main role is to maintain contacts with pharmacies, negotiate discounts and process claims and liaise with insurance companies, benefit program administrators, manufacturers and retailers to make adequate supply of safe and affordable drugs available to consumers.

Healthcare Plans and Insurance Providers

While the basic health coverage may be available through government-supported plans, additional coverage often becomes necessary in specific cases. Extended health coverage (e.g., serious illness, dental, vision, prescription drugs) can be obtained through employer benefits and personal insurance. Health care insurance providers offer extended health plans in exchange for payment of premiums by employers and individuals.

Healthcare Facilities and Retail Pharmacies

Retail pharmacies exist at the front end of a PSC before various drugs are delivered to patients based on a prescription. Pharmacies receive and store adequate supply of medicines to maintain a front-end inventory closer to the marketplace, and to sell and provide instructions to patients on how to consume the medicines.

RISKS AND OPERATIONAL CHALLENGES

The PSCs face several risks and challenges that bear on their ability to provide drugs in a timely and cost-effective manner. Besides the common risks and challenges such as drug counterfeiting and rising costs, there are several operational risks and challenges that PSC need to face.

Demand Management and Forecasting

Forecasting remains one of the biggest challenges for PSCs during the trial and the post-approval stages. The demand for pharmaceutical products is global and geographically spread out, making it hard to come up with an accurate and timely forecast. The uncertain nature of pandemics, social and market rumors, risky drug trials, and uncertainty about the approval make forecasting task challenging. The lack of visibility among different layers and the bull-whip effect further adds to this problem. The factors that influence the demand for pharmaceutical products are diverse and random in nature. Cultural backgrounds and lifestyle of patients also play a role in the demand for these products. All these factors combined add complexity to the forecasting process and affect the forecasting accuracy of pharmaceutical products.

Inventory

Pharmaceutical product inventory helps ensure a timely supply of life-saving drugs. The time dependent demand, shelf-life and product expiry of drugs, temperature and climate control requirements, shift in consumption patterns, product recalls, new inventions and break-through treatments, all play a role in deciding the inventory levels and develop inventory policies. For example, keeping the bulk storage inventory policy under the afore-mentioned conditions is a highly risky option when building inventory to ensure product availability for consumers and patients. Therefore, some risk pooling strategies will always be a part of an effective inventory policy.

Production and Distribution

The geographic diversification, freezing requirements, product design, lack of quality control staff, raw materials availability and scheduling difficulties pose unique challenges in both the production and distribution arenas of PSCs. Building and acquiring capacity ahead of time based on the market perception, perceived material shortages and competitors' actions adds an element of uncertainty into both production and distribution.

Coordination and reconciliation of push versus pull components of the supply chain remains a daunting and complex task. The raw materials, ingredients and some finished and semi-finished products with expiry life need to move based on push principles of supply chains. The market side requires a pull system based on demand in specific geographic regions. Various players and agents in the PSC working towards diverse goals make exigent demands on the supply chain planners. The sizing, location and selection of warehouse facilities and transportation equipment is another important aspect of PSCs.

Product Design and Development

Another issue in PSCs is selecting the right drugs to develop and manufacture that bring adequate profit margins. The manufacturing firms should be aware of the state-of-the-art research and stay in proximity with the cutting-edge research organizations and labs. Performing cost-benefit analysis for attractive profit margins on viable drugs, taking initiatives for timely approval with drug approval authorities, conducting efficacy studies, and making the product available in the market before completion are some challenging aspects of product design and development.

STRATEGIC RESPONSE

In Table 1 below, we outline response strategies that pharmaceutical companies can effectively utilize in mitigating the effects of the afore-mentioned challenges and risks. Typically, four risk management strategies are attempted in supply chains risk scenarios: risk elimination, acceptance, deflection, and mitigation. It may be noted that the above risks and challenges cannot be completely eliminated as most of them come from the environmental factors in this industry. The risk acceptance strategy in a healthcare environment where human lives and health is involved presents its own challenges. The deflection or insurance strategy is often either unavailable or too expensive to purchase. That leaves the mitigation strategy as a viable option. The impact of these risks on the supply chains can be mitigated or reduced to a level where management can effectively deal with these issues with adequate capacity. The choice, suitability and effectiveness of each mitigation action is problem specific and is based on several environmental factors. For example, geographic location of supply chain, degree and level of regulatory requirements, competitive landscape, healthcare structure, pandemic versus non-pandemic environment, level of risk involved all influence the choice of the right approach. Therefore, it is hard to prescribe a one-size-fits-all type of strategy in these settings.

TABLE 1
STRATEGIC RESPONSE TO CHALLENGES AND RISKS

Challenge & Risk	Response Strategies
Demand Management & Forecasting	Strategic use of technology; real-time demand modeling; point-of-sales data; improving global visibility through IT; Collaborative demand planning and forecasting approaches; reducing production, distribution and transport lead times; minimize price fluctuations; clearly convey the batch ordering policies across the supply chain.
Inventory Management	Maintain buffer stocks, decentralized field inventory at the front end; risk pooling with other locations; build agility & flexibility to move inventory around; balancing newer and traditional treatment options for patient care
Production & Distribution Management	Training of quality staff; use of technology in scheduling, product tracking and tracing; automation; accurate forecasting; back-haul empty miles transportation; flexible use multi-product warehousing; outsourcing, leveraging Government resources and distribution networks; achieving push-pull coordination at pre-defined critical and strategic points with adequate capacity
Product Design & Development	Cost-benefit analysis; value mapping and value engineering; leveraging global alliances; simplifying approval mechanisms, rapid prototyping and testing.

Pharmaceutical firms can benefit from strategic mapping tools to achieve their strategic goals and objectives. Table 2 below introduces one example of a mapping tool that the firms can benefit from. The exact application of the mapping tool may be specific to a firm and the problem environment. However, the approach should serve as a template for day-to-day decision making for managers and hence it has a value in ensuring that the strategic goals and objectives of the firm guide the operational decisions. Such an approach is strategic, measurable and practical for firms. The approach is sequential in the sense that efforts and contribution at each lower level leads to improved performance at a higher level and eventually contributes to the strategic goal listed at the top. The mapping tool is based on the balanced score card concept but adapted to the present environment. The sub-objectives under each goal are listed, the possible performance metrics are identified and the decision area where the strategic actions are needed are also mentioned in Table 2. The process starts with learning, training and development, which helps improve a firm's internal processes at a higher level. Further improvements to strengthen the internal process result in market gains at a higher level. These market gains improve the financial health of a firm and take it closer to its strategic goal.

TABLE 2
STRATEGIC MAPPING AT A FIRM LEVEL

Strategic goal. Timely delivery of affordable pharmaceutical products while ensuring sustainable profits

Goal	Objectives	Metrics	Decision areas
Financials	profits; revenue; costs	annual profit increase; % change in revenue; % reduction in costs; supply chain management costs; capital costs	revenue management; cost benefit analysis; budgeting; financial control & financial leverage
Market	market share; customer acquisition & retention; strategic alliances & partnerships	% market share; customer retention rate; new customers acquisition; newer alliances; newer products; customer satisfaction	promotional budgets; R&D, customer service; complaint mechanisms; partnership agreements; mergers & acquisitions
Internal processes	product design, development and delivery; promotional activities; customer relationship management & customer support	product line; lead time; time to market; production & distribution costs; promotional impact; defect rates; late deliveries; customer complaints management	streamlining designs; economical and safe packaging; operations; storage; transportation; inventory management; quality management; brand recognition
Learning & Development	R&D; supplier development; core competencies; develop employee base, develop IT capabilities	newer products; new suppliers; supplier ratings; skills development; training programs; IT efficiency; employee satisfaction	product line management; supplier selection & supply base; knowledge management; HRM; developing IT base

CONCLUDING REMARKS

This paper focuses on the unique challenges faced by the pharmaceutical industry and underlines the key role played by operations and supply chain strategies in efficiently managing pharmaceutical supply chains. The paper provides a generic structure for a pharmaceutical supply chain and investigates the major issues, risks, trends and challenges faced in the pharmaceutical industry. For each category of risks and challenges, some operations response strategies are suggested for the pharmaceutical supply chains. Due to many variables and environmental factors, uncertainty and uniqueness inherent in PSCs, it is hard to prescribe a one-size-fits-all strategy to deal with these challenges. However, several operational response strategies are identified in this paper to deal with specific issues. The management can apply these strategies based on the merit of the event, severity and frequency of the risk involved and can effectively mitigate

some of these challenges. A strategic mapping tool that links strategic goals, objectives, metrics, and decision areas sequentially is also suggested. Therein lies the contribution of this work.

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