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CHALLENGES AND RISKS ASSOCIATED WITH PHARMACEUTICAL SUPPLY CHAIN. A SYSTEMATIC REVIEW.

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Abstract

The pharmaceutical supply chain poses risks and challenges to both providers and consumers. But in the context of a health-conscious society, managing pharmaceutical supply chains presents several complexities because it involves many key components and stakeholders to efficiently deliver life-saving medicines that are vital to patients. In such a complex process, the stakes are high for pharmaceutical companies. Incorrectly distributed drugs can harm their reputation, customer satisfaction, and potential profits. The purpose of this review is to break down the fundamentals of the pharmaceutical supply chain to uncover strategies for overcoming the most common challenges and ways to get patients, consistent access to current and new drugs. Bibliographic databases such as PubMed, Scopus, Web of Science and scientific search engines such as Google scholar, were searched for pharmaceutical supply chain risk management studies carried out until January 2022.

Keywords- Supply chain, pharmacy, challenges, PBM

Introduction

Supply chain management (SCM) is defined as the integration of key business processes across the supply chain for the purpose of creating value for customers and stakeholders [1].

Ensuring access to medicine is considered a fundamental human right and is a primary goal of healthcare systems [2]. The pharmaceutical supply chain must ensure the delivery of medications in the appropriate quantity and acceptable quality to the correct location and consumers, within the specified timeframe and at optimal cost. This is essential to align with the aims of the health system and generate advantages for the company's shareholders [3].

Any risks affecting the pharmaceutical supply chain, not only can waste the resources but also can threaten the patients' life by hindering access to medicines [3]. Risk management is not only important in the pharmaceutical supply chain, but also is a major player in other aspects of pharmaceuticals such as prescription and uses of medicine [4, 5]. Assessing and implementing the strategies to manage the risks in pharmaceutical supply chain is essential in health systems [6]. The importance of the risk management is becoming more vital because medicine is a highly regulated product which is under the controls and tight limitations of public regulatory authorities [7]. Also supply of medicines as strategic goods in developing countries with much economic, social and political instability is faced with more uncertainties and vulnerabilities [8].

The pharmaceutical industry supply chain's key stakeholders include raw material suppliers, drug makers, regulatory agencies, wholesale distributors, pharmacies and pharmacy benefit managers (PBMs), healthcare providers, and patients. Each stakeholder plays an important role, and appropriate coordination among them is required [9].

In such a complex process, the stakes are high for pharmaceutical companies. Incorrectly distributed drugs can harm their reputation, customer satisfaction, and potential profits.

According to a Kaiser Family Foundation report, an ineffective supply chain can also disrupt patients' healing processes and have adverse effects on public health.The pharmaceutical supply chain faces several challenges, including supply chain visibility, drug counterfeiting, cold-chain shipping, and rising prescription drug prices, which can significantly increase patient costs [10].

Aim

The purpose of this systematic review is to break down the fundamentals of the pharmaceutical supply chain to uncover strategies for overcoming the most common challenges and risks and ways to get patients, consistent access to current and new drugs.

Materials and Method

Bibliographic databases such as PubMed, Scopus, Web of Science and scientific search engines such as Google scholar, were searched for pharmaceutical supply chain risk management studies in English language. Searching through databases was done with different keywords: Supply chain management, risk, risk management, risk assessment, pharmaceutical. Searching in each database was adapted to databases characteristics and additionally Medical Subject Headings (MeSH) in searching through PubMed was considered. The last version of searching in mentioned databases carried out in the first week of January 2022.

Results

A total of 357 articles relevant to the topic were identified from databases.All results (studies and meeting abstracts) were screened by 4 steps: 1. All results titles were reviewed and none-relevant articles were excluded by outcome of interests and researcher boundaries of study; 2. As some of the articles were found in different databases and also they were duplicated via different groups of keywords, duplicated articles were excluded; 3. After screening the articles, abstracts of all remained articles were reviewed and the none-relevant articles, based on study boundaries, were excluded; 4. In the final step, full texts of all remained articles were read and some of them were excluded by outcome of interest.The exclusion process was based on consensus of all the authors. Piloted form used for extracting risks from studies.

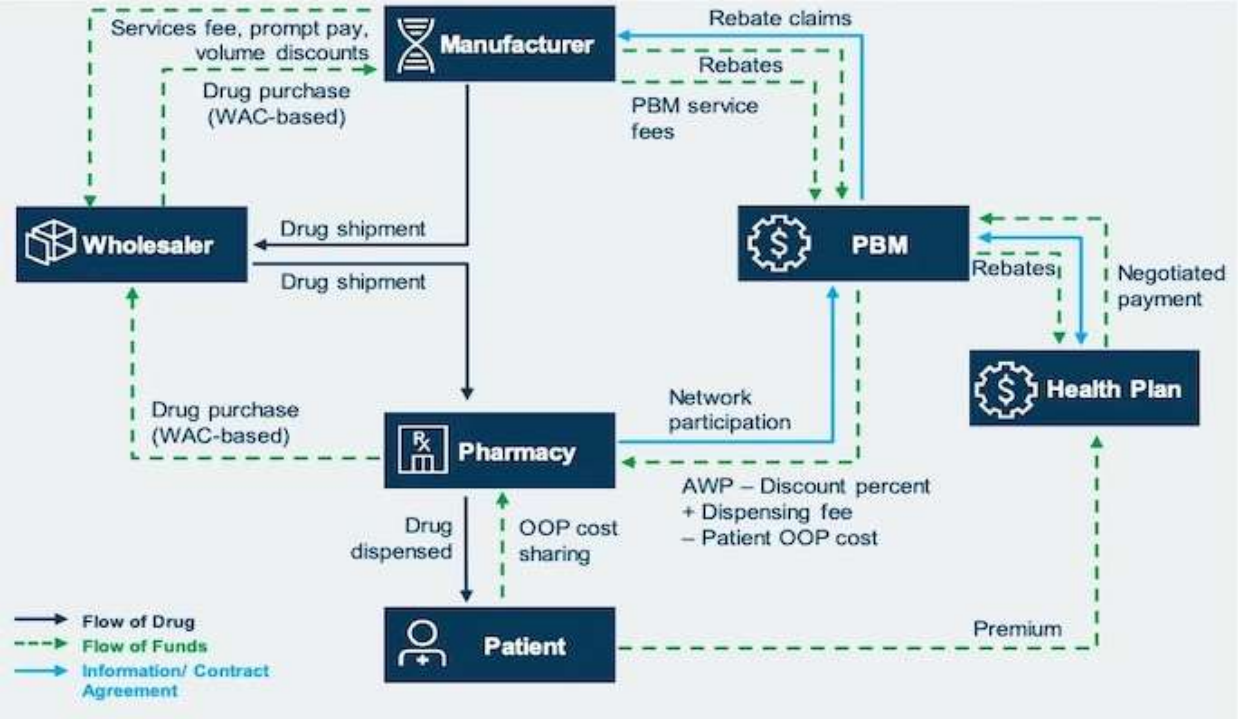
Discussion

The pharmaceutical supply chain poses risks and challenges to both providers and consumers. But in the context of a health-conscious society, managing pharmaceutical supply chains presents several complexities because it involves many key components and stakeholders to efficiently deliver life-saving medicines that are vital to patients.

The pharmaceutical supply chain involves the process of sourcing raw materials, manufacturing, distributing, and delivering medications to patients. Because the pharma supply chain network

comprises various stakeholders, it requires careful coordination and adherence to regulatory guidelines at every stage to ensure patients receive safe and effective medications [11].

The following Avalere diagram depicts the general path a prescription drug usually takes through the drug supply chain in a standard retail pharmacy distribution. It is important to note that this chart does not consider the nuances of physician-administered drugs or specific products or entities.



Source- Avalere

As noted in Kaiser Family Foundation report (https://www.kff.org/wp-content/uploads/2013/01/follow-the-pill-understanding-the-u-s-commercial-pharmaceutical-supply-chain-report.pdf), the following five pharmaceutical supply chain strategies ensure that drug inventory is readily available for distribution to providers and patients:

1. Drugs are manufactured at production sites.
2. They are then transferred to wholesale distributors.
3. The pharmaceuticals are stocked at various types of pharmacies, including retail and mail-order.
4. Pharmacy benefit management companies negotiate prices and process drugs through quality and utilization management checks.
5. Finally, pharmacies dispense the drugs to patients, who take them as prescribed.

Researchers note there are many variations on this basic structure of the pharmaceutical supply chain, mainly due to the constantly evolving players. The vital players of the pharmaceutical supply chain network allow it to run smoothly and efficiently. Those players include manufacturers, wholesale distributors, pharmacies, and PBMs.

Pharmaceutical manufacturers aim to supply a number of finished products that match the demand from the pharmaceutical sector. These manufacturers are responsible for distributing drugs from their facilities to drug wholesalers or directly to various types of pharmacies, including retail chains, mail-order and specialty pharmacies, hospital chains, and certain health plans [12].

Notably, pharmaceutical manufacturers have the most influence over pharmaceutical prices, assessing expected demand, future competition, and projected marketing cost to establish the wholesale acquisition cost (WAC), according to researchers.

Wholesale distributors purchase pharmaceutical products from manufacturers and distribute them to various customers, including pharmacies. While some wholesalers cater to a wide range of clients, others specialize in the sales of specific products like biologics or cater to particular types of customers.

Pharmacy Benefit Manager (PBMs)

Although not a direct link in the physical supply chain for pharmaceutical products, PBMs are intermediaries that work with health insurers, employers, and government programs to manage prescription drug benefits for patients. PBMs negotiate drug prices with drug manufacturers, determine which drugs are covered by a patient's insurance plan, and manage formularies (lists of covered drugs) [13].

They also negotiate drug prices with pharmacies, process claims, and provide medication therapy management services to patients. Ultimately, PBMs play a critical role in controlling prescription drug costs and ensuring patients have access to safe and effective medications. In Saudi Arabia and other developed countries roughly two-thirds of all prescriptions written are processed by a PBM.

Pharmacies are the final step in the supply chain before drugs reach the patient — arguably the most vital step because they serve as the information link between PBMs, drug manufacturers, and wholesale distributors. Pharmacies purchase drugs from wholesalers or directly from manufacturers. After purchasing products, pharmacies must maintain an ample stock of drug products and provide information to consumers about the safe and effective use of prescription drugs [14].

The pharmaceutical supply chain plays a significant role in determining drug costs. Without good partnerships, oversight, and supply chain management, consumers face higher out-of-pocket expenses and health plans deal with higher drug spending.

Another factor that can impact drug costs is the cost of production. Because manufacturers must cover the costs of research and development, clinical trials, and regulatory approval before they can bring a drug to market, those costs are often passed on to consumers in the form of higher drug prices [15].

The supply and demand of the drug are also other factors that control drug pricing. If a drug is in high demand and there is a limited supply, the price may be higher. If there are few competitors producing a particular drug, this can lead to higher prices as well.Researchers note that a rise in high-deductible or coinsurance health plans has resulted in an increased number of patients facing higher out-of-pocket expenses. Consequently, these patients may not benefit from negotiated prices, as their co-payment is based on the listed price of the medication rather than the negotiated cost [16].

As per a study by the National Community Pharmacists Association (NCPA), elevated prices of generic drugs have had negative consequences for almost all stakeholders in the pharmaceutical supply chain. Consumers are experiencing a surge in co-pays and prices, while health plans are grappling with escalated drug spending. Physicians are compelled to prescribe alternative drug therapies, and in some cases, consumers are refusing medication due to the soaring prices [17].

Pharmaceutical supply chain challenges

By conducting numerous interviews and surveys with professionals in the global health supply chain, researchers from *Operations Research for Health Care* have outlined the 10 most significant challenges faced by the pharmaceutical supply chain, including (1) coordination issues, (2) inventory management, (3) inadequate demand information, (4) reliance on human resources, (5) order management, (6) avoiding drug shortages, (7) drug expiration, (8) warehouse management, (9) temperature control, and (10) shipment visibility.

The pharmaceutical supply chain encounters multiple other challenges that may result in delays, shortages, and wastage if not efficiently handled. Efficiently managing all challenges necessitates effective communication, collaboration, and meticulous inventory and resource management throughout the supply chain [18].

Forrester effect

The "Forrester Effect" or the "Bullwhip Effect" is a vital business analysis technique that shows the relationship between the increase of the variability of the client demand and the length of the supply chain. This supply chain phenomenon refers to the demand variability amplification that can occur as orders move up the supply chain from the end customer to the manufacturer.

However, because this effect is most often seen at the primary manufacturing site, which is the least responsive part of the supply chain, it can result in significant inefficiencies — including excess inventory, stockouts, and higher costs. This makes it difficult for businesses to adequately address healthcare system challenges such as supply shortages, tenders for national supplies, and epidemics.

Researchers from Northeastern University and MIT Sloan School of Management also recently noted ways to tackle drug shortages. The research article published in *Complexity* stated that one common solution was to keep more inventory to ensure that more products are available to treat patients in the event that products are recalled [19].

According to a report from researchers at the Imperial College of Science, Technology, and Medicine, all businesses with an efficient supply chain strategy follow a four-step process:

1. Demand management
2. Inventory management and distribution
3. Secondary production planning and scheduling
4. Primary manufacturing

Additionally, the researchers noted some tactics for eliminating the effects of disruptions, including financial mitigation, operation mitigation, and operational contingencies.

More specific challenges reported by researchers at the Imperial College of Science, Technology, and Medicine included uncertainty in the pipeline of drug development and new products — specifically, which drugs will be successful in clinical trials and what sort of drug administration and dosages are optimal [20].

Digitizing the Supply Chain

The utilization of technology in supply chains has become increasingly crucial due to the combination of a more digitalized world and ongoing operational disruptions. Using digital tools helps reduce costs, enhance efficiency, and strengthen resilience but also aids in managing risks and tackling environmental, social, and governance (ESG) concerns [21].

In the past, PwC has noted that — to meet the growing marketplace's demands — the pharmaceutical supply chain must undergo a “radical overhaul.” The radical overhaul, according to researchers, includes more diverse product types and therapies with shorter lifecycles, new ways for assessing, approving, and monitoring medicines through the FDA, increasing emphasis on outcomes, new models of delivering healthcare, and various other changes [22].

Overall, the pharma industry and its supply chain are vital for patients to receive the medications they need without dealing with stress or roadblocks. Although the supply chain faces various challenges, companies can take the necessary steps to ensure a smooth process from the manufacturing of products to the delivery to patients.

Conclusion

The performance of pharmaceutical firms as a key participant in the pharmaceutical supply chain has a substantial impact on the efficiency of supply chain management. Identifying and managing risks in pharmaceutical firms can result in process optimization, increased productivity, and reduced business risk. Additionally, it can assist health systems in achieving the objectives of supply chain management, namely accessibility, quality, and affordability. The study identifies numerous internal hazards resulting from mismanagement of processes, people, and roles within a corporation. These risks can be effectively addressed through appropriate mitigation techniques. While the impact of external risks on business disruption has not been thoroughly examined, it is important to note that only a few of these threats are external in nature. Hence, it is imperative to analyze the potential consequences of risks on business processes and operations, and explore effective strategies to mitigate them. This aspect should be taken into account in future research endeavors.

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