Role of pharmaceutical supply chain in system approach to provide useful problem ...

Business, Management

An entire supply chain is like a story and person managing it is the story teller. This story consists of characters such as the ones purchasing the raw materials, items and equipment used in creating the product and means of getting the item to the end consumer.

As with any other story, a consumer expects this story to have a happy ending. It requires a high degree of skill, dedication and collaboration to make possible this happy ending for the consumer. The first step in any supply chain is Procurement. Procurement is the action of obtaining equipment or materials for a business. It is an act of choosing the appropriate supplier who suits the requirements. The next step in the supply chain is Manufacturing and Operations. In this part the system moves from gathering material to actually making something. Here the biggest task is to consider the time constraint. Operations managers in large companies strive towards putting together the supplies quickly and also, on a day-to-day basis. The third step in this process is Logistics and Transportation. It is the commercial activity of transporting finished goods to customers. The responsibilities here include protecting the product from the outside world, packaging, containerization and actual transportation. Supply chains buy things, make things and move things. This is a complex process when scaling is considered. Dealing with thousandsof items/day, variety, special orders, health regulations, etc. are the challenges faced by supply chain managers across the globe.

Purchases made by a consumer goes through a complex process in which various microscopic components interact with each other non-linearly to

produce an emergent and over time self-organizing system. Emergence and self-organization are two of the main properties in today’s real-world complex systems. Emergent systems are those in which the properties change when viewed at different scales. The properties of the individual components of the supply chain are different from those in which all the components interact with each other to form a collective behaviour. It simply refers to existence or formation of collective behaviours – what parts of the system do together, what they cannot do alone. Self-organization refers to the growth of the system by deliberating on the failures. Over-time the complex system keeps getting better and better at what it isdoing by learning from its mistakes and fixing them. This report considers the Pharmaceutical Supply Chain as a complex system to explain the use of systems approach to provide useful solutions to existing challenges.

The drug supply chain involves a number of stakeholders, from the manufacturers who create drugs, to the pharmacies that distribute them, to the PBMs that oversee the process.

1. Manufacturers: They are the ones who carry out R&D to produce drugs. Examples: Roche, Novartis, and Pfizer.
2. Payers: These are the entities other than patients that pay for care. These are usually the insurance companies. Examples: UnitedHealth Group, Aetna and Anthem.
3. Pharmacy benefits managers (PBMs): Mediators between the payer clients and manufacturers for the purpose of drug prices negotiations. Examples: American Health Care, Cigna and AmWins Rx.

4. Wholesalers: Procure in bulk from pharmaceutical manufacturers and distribute them to pharmacies. Examples: AmerisourceBergen, Cardinal Health and McKesson.

   Pharmacies: Receives distributions from wholesalers and sell drugs to the patients. Examples: CVS, Walgreens, and Walmart.

5. Speciality Pharmacies: Deal with the distribution of uncommon or fragile drugs. Examples: CVS Speciality and Alliance Rx.
6. Patients: The user of the drugs. Flow of Drugs: Manufacturers produce drugs and sell them in large quantities to wholesalers. Wholesalers use complex logistics and packaging methods to receive and deliver drugs on a strict time schedule and in the condition, it is meant to be consumed at the pharmacy. Pharmacy then sells the drugs to the patients. Patients can either go to the pharmacy to pick up the drugs or get it delivered directly to their homes.

The collective experience and wisdom of global health supply chain professionals through interviews and surveys have helped to identify and prioritize the top 10 global health pharmaceutical supply chain challenges: (1) lack of co-ordination, (2) inventory management, (3) absent demand information, (4) human resource dependency, (5) order management (6) shortage avoidance, (7) expiration, (8) warehouse management, (9) temperature control and (10) shipment visibility. Lack of co-ordination leads to all the other challenges mentioned above. Large companies with revenues of tens of billion dollars do not have full insights into their supply chains from end-to-end. There is a need for system’s approach by means of a unified

dataset that connects the pharmaceutical business, the inner workings of the enterprise strategy to tackle the challenges faced in the industry. Currently the decisions are made by the best possible data and tools but it could be much more powerful and could also be automated if digital transformation is leveraged. For example, German Pharmaceutical company Merck KGaA, by placing sensors throughout its supply chain gathered real-time data about inventory distribution practises and availability for every stock keeping unit. This helped them achieve end-to-end visibility, process order in the shortest possible time which in turn optimised their operations. AI, when leveraged into the pharmaceutical supply chain can process huge amounts of real-time data which include inventory data, supplier performance, demand fluctuation and even bad weather conditions and give the companies intelligent recommendations. It will turn the entire complex system into a self-driving business based on cognitive automation which makes decisions optimal. As predictive capabilities are getting more and more powerful, those companies who adopt applications of AI in the early stages will sustain and those who hamper this progress will have the risk of falling behind. Companies such as Johnson & Johnson are seen leveraging smart phone apps for the purpose of giving patients a clinical trial. Janssen, a subsidiary of Johnson & Johnson have designed a system which scans the shipments at various sites in the supply chain to prevent dispensation error. The system also ensures the patient uses their medications. The smart phone app features instructional videos, to know how to take it. Also there are smart blister packs which gives the trial investigators to know when the drug pills are taken out of the packet.

Biologics are an upcoming type of pharmaceuticals which includes vaccines, blood and blood components, and gene therapies which require to be transported using the cold chain. Identifying whether these products have been maintained under proper temperatures in the cold chains, or have been exposed to sunlight is a huge challenge. A solution for this could be the use of thermochromic paint labels on the medicine’s packaging which indicates exposure to certain temperatures or UV light by changing the color of the labels. Also, there are certain paints which can be applied to the medicines packaging which indicate the change in color only if observed using certain eye-equipment.

Flow of Services and Money: PBMs, manufacturers and insurers collaborate to develop a list of drugs called formularies to be covered by insurers. One main negotiation carried out by PBMs is that it gives a certain manufacturer’s drug a preferred placement on its formulary in exchange for discounts and other incentives. Payers cover a portion of drug costs on prescription drugs. Flow of money in a pharmaceutical supply chain is complex and requires the application of system’s approach to come out with solutions to the current challenges. Literature below shows how the money runs through a drug supply chain.

1. Patient: Pays premium to the insurer and barters health coverage. Pays a co-pay to PBMs when purchasing drugs at the pharmacy. Patient may or may not receive co-pay assistant from the manufacturer when purchasing a certain drug.

2. Pharmacy: Pays the wholesaler while buying drugs. Also gets negotiated payment from its PBM when it sells drug.
3. Wholesaler: Pays manufacturers when buying drugs in large quantities. Receives payments from pharmacies buying the wholesaler’s drug inventories.
4. PBM: Negotiated payment goes to pharmacies from the PBM when a patient purchases at the pharmacy. Receives payment from payers, patients and manufacturers. Payers pay the PBM for the negotiation services. Patients pay the co-pay and manufacturers offers discounts and incentives to PBMS in exchange for marketing their drugs.
5. Manufacturers receive payments from wholesalers and may pay co-pay to the patients in the form of co-pay assistance to incentivize purchase of drugs.

With this it can be extrapolated that the flow of payments in the traditional pharmaceutical supply chain is complex and inefficient and because of this prescription drugs cost is on the rise. For every $100 spent by the patient on prescription drugs $41 goes to intermediaries in the supply chain.

Also, the plan sponsor, often an employer who takes financial risks for their employees and eligible dependants works with a benefit consultant to evaluate a prospective PBM. The PBM offers the plan sponsor with a pharmacy benefit solution which includes (1) a retail network, (2) mail order capabilities (3) drug quantity purchasing discounts, (4) clinical analysis, (5) eligibility determination and tracking, and (6) claims adjudication. The PBM pays the contracting parties and makes profit from the excess revenue

generated from the payment received from the plan sponsor. The issue here lies in the fact that the plan sponsor does not hire the PBM to deliver the products and services at a fixed unit cost, but hires the PBM just to manage the pharmacy benefit program. Moreover, the financial risk of cost increase and excessive or unanticipated utilization is taken by the plan sponsor. Also, the PBM who has a better knowledge about the drug supply chain as compared to the plan sponsor, the plan sponsor does not have a clarity in terms of ensuring that is PBM is always acting in the plan sponsor’s best interest. One of many the challenges faced by the plan sponsors is package size pricing. The PBM purchases the drugs in bulk say 50, 000 or greater and get them at a significantly cheaper price. The PBM offer the plan sponsor a percentage discount to the average wholesale price (AWP); e. g., 16 percent off AWP for brand named drugs which is based on package size, say 100 pills or even less in some cases. The PBM can now say that it saved money for the plan sponsor some percentage off of AWP, whereas the PBM is getting the drugs for a significantly lesser price. There are many incidents where patients have realised that they have to spend lesser on drugs if they spend out of pocket than if they use their insurance plan. The main reason for this is that the difference in the cost does directly to the PBMs as a co-pay. An innovative approach derived from the experiences and efforts of Caterpillar, Inc. to address these issues is to remove the PBM as the controlling organization in the prescription drug supply chain. The plan sponsor needs to limit the PBMs role in the contract in managing the drug supply chain.

Also, start-ups such as GoodRx and Blink Health are raising funds and could potentially reduce the role of PBMs, negotiating discounts for manufacturers selling to pharmacies or patients.

Drug Counterfeiting: Drug counterfeiting is also a huge issue in the supply chain. Patients buying a packet of pills rarely think about its authenticity. In 2009, 34 million counterfeit tablets had been taken out of circulation in Europe in just a two-month period and is a significant threat to populations around the world. To combat this public health problem, new regulations have been put in place which require that the drugs should be serialized, beginning from the manufacturer and must be verified before the handoff takes place. But this need a centralised track and trace approach which is practically expensive and unsecure. Technologies such as Blockchain also known as distributed ledger technology are poised to offer an alternative to traditional centralized track and trace solutions. This sort of system’s approach creates a network of transaction ledgers, in this case the creation and transfer of ownership of serialized packages of drugs. Each company has its own copy of ledger. When packet of drug reaches one member from the other in the supply chain, each member of the chain is notified and each member of the supply chain verifies that the transaction is valid. The security is also much more powerful as once the transaction is added to the ledger it is unfeasibly difficult to alter it. Also, nowadays there are special inks which indicate expiry of medicines or usability or all kind of indication about the current state of the product as mentioned in the literature above.