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Supply Chain as a Core Component of Business Model: Innovative Supply Chain Practices in Pharma and Radiopharma Industries

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Abstract

In the 21st century, the Pharma market has changed significantly. The companies worldwide are forced to reconsider their business priorities and strategies in order to handle the uncertainty, volatility and complexity. In line with this development, the companies in pharmaceutical market have realized the importance of effective supply chain management. This review article aims to discuss the importance of supply chain management within pharmaceutical and radiopharmaceutical industries. After introducing several basic concepts in supply chain research field, we will discuss the differences of supply chain between Pharma/radiopharma industries and other industries and the challenges faced in the focus industries. Different states of art supply chain management models, developed by several major companies in both industries, are evaluated in order to support the future's successful businesses.

Introduction

There is no doubt that like other markets, Pharma market has changed significantly in the 21st century. The features characterize 21st century market are: high level of uncertainty, strong competitive environment, shorter product life cycle, unspecified demand and unreliable supply [1]. So companies have to handle the uncertainty, volatility and complexity to improve their profits [2]. Although volatility is the active ingredient, complexity and uncertainty have larger effect than volatility. Globalization is the key volatility leading further to product complexity [2]. There is no doubt that, in today's increasingly competitive business environment, it is no longer possible for any company to exist only with internal functions' optimization and improvements. Enterprises have realized that they can no longer control all sources necessary for full satisfaction of market demand. Therefore, companies have to reconsider their business priorities and strategies.

The pharmaceutical market is a unique and complex system characterized by highly regulated environment coupled with the high value products. Although outsourcing is not shown as the biggest challenge faced by Pharma market [1], interest on supply chain management has rapidly increased in recent years. One of the most important reasons of this increase is that companies have already reached the point where the production costs are in optimum level. Therefore, the companies have realized the fact that unless they manage the supply chain effectively, they can no longer obtain any savings from their cost [3].

For a multi-billion industry that manufactures and distributes products to millions of people every day, supply chain management strategies that interact with all steps–development, manufacture and distribution- are worth to discuss, and state of art models must be evaluated deeply to support the future's successful businesses.

Supply Chain Management and the Concept of Agility and Responsiveness

According to the Supply Chain Council (SCC) [4], supply chain management includes: 1) managing supply and demand, 2) sourcing raw materials, 3) manufacturing and assembly, 4) warehousing and inventory tracking, 5) ordering management, 6) distribution to channels, and delivery to the customer.

Although supply chain management concept is the same, different industries have different supply chains as they address different needs. For example, while for the computer industry, the main need is the product configuration flexibility with minimum cost; it is product variability for consumer goods industry. Therefore, although the end goal is the development of competitiveness; industry-based evaluations should be done to ensure efficiency and effectiveness.

The results of one pioneering project "Supply Chain 2020" conducted by the MIT Center for Transportation and Logistic is worth to highlight here [5]. The aim of the project is to identify and analyze the factors that are critical to the success of the supply chain, and to map out the innovations that support the 2020's successful supply chain [6]. According to the results of the study, the success of the supply chain is defined as not only resulting from benefits including tangible cost savings or similar measurable metrics, but also from successful practices in business environment with different needs and changeable conditions [6]. Responding rapidly to changing business needs and environment can be achieved by flexibility, which is the main characteristic of agility concept [6,7].

Agility implies responsiveness from one end of supply chain to the other. It focuses on eliminating the organizational or technical barriers to quick response [8]. Agile supply chain is distinguished by flexibility, adaptability and quick as well as effective response to the changing markets. Christopher and Towill [8] define the distinctive features of agile supply chain as: 1. Responsiveness: ability to identify changes and respond quickly and proactively. 2. Competency: ability to implement the goals of the firm effectively and efficiently. 3. Flexibility: ability to implement various processes and adapt to different conditions. 4. Speed: ability to achieve results as quickly as possible.

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Pharmaceutical Supply Chain Structure and Today's Challenges

The Pharma industry, as old as mankind, has evolved over time parallel with the evolution of human being. Throughout this evolution organizational side of the industry was also developed. Especially after 1990's, noticeable structural re-organization including drug discovery, clinical trials management, drug launch and marketing, production, distribution, and drug delivery mechanisms was observed in pharmaceutical industry [9]. With this reorganization, industry was opened to contest, and leading companies lost their dominance. Alongside this reorganization, business models shifted from the blockbuster drug model, to a more stratified personalized medicine model.

Pharma industry is unique with its complex structure which is differentiated from other industries by 1) Anatomical structure: although the last consumer (customer) is the patient; because of its association with health care system other decision makers (who make purchase decision and make payment decision) are also called consumer. Berndt summarizes this anatomical structure as illustrated in (Figure 1) [10]; 2) Product and services: the products and services offered by the pharma industry are very different in nature; 3) Pricing: the pricing and the flow of money is more complex than the physical distribution of product (drug) through chain [11]. This atypical dynamics result in strategic and operational differences in Pharma industry among other industries.

When the unique feature of product development process is taken into consideration (Figure 2), Pharma industry has to have two different types of supply chain with different capabilities: one that supports development and launch, and other to sell a drug in the market. While the first one aims to quick completion of pre-clinical and clinical tests together with the approval of the drug product, the second aims to meet the sales target [6].

In the development and launch phase, the major complexity is the forecasting of demand. Therefore, supply chain must quickly respond to the changes of demand. Here the key factor in the success is the agility and responsiveness. After launching the drug, different drivers and complexities become dominant. As a result, the focus shifts from agility

Convoluted Health care System

- Person "A" goes to a local franchise restaurant, and sits down at the table to eat
- Person "B" arrives, looks at the menu, and places an order for "A"
- "B" orders a Diet Coke for "A", but is told the restaurant only offers Diet Pepsi, not Diet Coke
- "B" leaves, and "A" consumes his/her meal
- "A" pays only 15 % of the restaurant bill, then leaves
- "C" from Aggregated Eaters, Inc. Arrives, picks up the restaurant bill, demands a volume discount, and then pays the restaurant the discounted amount. *This is U.S health care!*

Figure 1: Anatomical structure of U.S health care system [10].

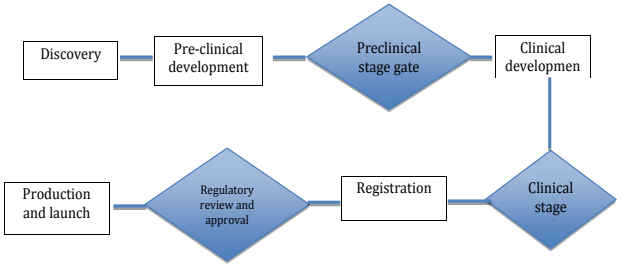

Figure 2: Basic pharmaceutical drug development process.

to the high availability. The major complexity at this phase is having multiple stakeholders diverse in nature such as, regulatory authorities, governmental agencies, hospitals, retailers, pharmacies, wholesalers, distributors and manufacturers [6].

In addition to these complexities, major challenges faced by the pharma industry are [12]:

Increase in cost of drug development: As a result of economic conditions of today, cost of drug development is increasing day by day. This puts more pressure on sales to compete with these costs, which results in more inventory. Moreover, in order to decrease the costs, companies have shifted their drug development business to developing low-cost countries. However, technical and regulatory competencies of these countries are still questioned.

Decline in R&D productivity

Shifting trends from traditional medicine to the personalized medicine triggered dramatic changes in R&D activities, and resulted in the need of development of innovative drugs. Despite 4 times increase in R&D expenditures over the last decade, new molecular entities and biologic license applications, which are the indicators of R&D productivity have decreased. According to the 2004 report of FDA, the number of approvals for 2003 was almost half of the 1996's [13]. The big pharmaceutical companies responded to this problem by mergers and/or acquisitions, which can not be considered as exact solutions since in the long run these mergers and/or acquisitions has brought more complexities.

Changing market conditions

As a result of increased costs of drug development, there is no doubt that, the growth of pharmaceutical companies relies on emerging market. Absence of stringent patent norms in emerging markets will result in longer supply chain in order to safeguard formulation techniques. This makes supply chain more prone to quality problems. Moreover, logistic cost of emerging markets is more than 3-fold higher than the developed markets.

Rise of generic market

As a result of patent expiration of blockbuster drugs, generic market has been growing rapidly. This leads to more pressure to lower the prices. Moreover, regulatory authorities are encouraging generics competition. This means increased risks and uncertainty for pharmaceutical companies. According to industry estimates, cumulative potential risk of sales at $290 billion over the next five years [14]. Under this pressure pharmaceutical companies need to lower the production costs.

Safety issues

The increasing globalization is counterfeiting and drug recalls are becoming important safety issues. According to the FDA, reported security incidents such as counterfeiting, theft and diversion of prescription drugs rose by 4-fold in the last decade. Similarly, the increase in the number of reported Adverse Drug Reaction (ADR) is becoming very worrisome. In 2010, Uppsala Monitoring Centre (UMC)'s database contained over 4 million reports from over 100 countries [15]. In the financial aspect, one scrapped batch represent between 3-5 M $ to the company [16]. In addition, from the operation standpoint removal of every unsold drug from every point in the supply chain by reverse logistic is a major challenge.

Innovative Supply Chain Management Practices in Pharma and Radiopharma Industries

Pharmaceutical industry

In early 2000's, parallel to the expansion in business scope (Table 1) [6] Elli Lilly launched many industry-leading products while the majority of drug manufacturers faced a decrease in R&D productivity [13]. Elli Lilly's distinguishing characteristic of R&D business strategy, on the contrary to merger or acquisition (like Pfizer), mainly depends on in-house R&D capabilities.

There is no doubt that these launches were the results of several actions taken to improve productivity and R&D capacity. Other actions taken to rationalize its infrastructure, such as capacity addition, upgrade and reconfiguration, were also important. All these actions taken resulted in reshaping supply chain infrastructure of the company. That is why it is worth to discuss here.

Before discussing Elli Lilly's success in detail, let's see the infrastructure of Lilly's supply chain. Lilly summarized this process as having 100-250 days of active processing time as follows [17]:

- Make Active Pharmaceutical Ingredient (API)
- Store/ship API
- Make formulation
- Store/ship semi-finished product
- Package finished product
- Store finished product (Figure 3)

Two important components play key role in shaping of supply chain infrastructure: storage and regulatory obligations. First, due to the sensitivity of chemicals to storage conditions and limited self-life, warehousing of raw material and finished products affects the manufacturing process. Second one is, together with warehouses (raw material, bulk, semi-finished and finished product) all sites included in the manufacturing of a drug must be approved for Good Manufacturing Practices (GMP) by regulatory authorities. As a result, switching of products and/or sites is not easy at a short notice.

One approach is to simultaneously register multiple sites for multiple products, which is called "Manufacturing Network" by Lilly (Figure 4)[6]. Briefly, this model can be outlined as reducing in house operations and conducting remaining activities externally via carefully selected, risk managed portfolio of straight outsourcing arrangements and strategic alliances [18]. Major advantages of this model are [6]: 1) agility: in a network community, a company can respond to the changes in demand and supply. As discussed above, when the unique feature of product development process in pharma industry is taken into consideration especially in the development phase, responding faster to changed demand gives flexibility to further steps. 2) lead time reduction: for the same aforementioned reason, a networked company responds quickly to a problem or opportunity. 3) rapid market access: with this model companies can form or dissolve alliances as desires resulted in easier entering or existing in a market. 4) Better resource utilization: a company can improve its utility by improving resource management.

Indeed this strategy increases the complexity and the cost of the system, but the benefits far outweigh the additional costs. With this strategy, supply chain management becomes a key component of corporate success, hallmarked by Supply Chain 2020 Project [5] as "excellent supply chain". In this concept, the main objective of the supply chain is to balance customer service level, cost, flexibility and risk management to fit the marketplace needs of each product. Lilly follows two steps [17]:

Supply chain design: The key objective is to manage the risks. The biggest challenge is the extreme demand uncertainty. In addition, highly stick and long registration process, little flexibility in production give designer limited options. Lily uses 3-step process 1) capacity strategy and sourcing (finding portfolio) 2) sourcing optimization 3) final decision (decision on walk with third party or not to increase revenue)

Supply chain operation: The key objective is to maintain 100% customer service level and profit maximization which can be achieved by concomitant steps: 1) demand management 2) inventory, risk and customer service level 3) supply chain planning 4) global capacity balancing and profit maximization 5) launch management 6) operational excellence. The operated model at Lilly is fully integrated into business and innovation is the key of business strategy.

As a summary, Elli Lily's successive supply chain is based on tight fitting of supply chain process with its business strategy. As discussed above the biggest uncertainty in the drug development process is the launch. Therefore forecasting the demand is the major challenge faced in the supply chain operations. As a result capacity planning is the key step. In this step building flexibility can solve the capacity issues. Lilly achieved this with "manufacturing network" strategy by using its assets effectively.

Radiopharmaceutical Industry

Radiopharmaceuticals are any medicinal products which, when ready for use, contain one or more radionuclides (radioisotopes) included for a pharmaceutical purpose. The European radioisotopes market valued $1.1 billion in 2012 and is poised to reach $1.6 billion in 2017 at a CAGR of 6.8% [19]. The market of radiopharmaceuticals is broadly classified into two segments, namely diagnostic and therapeutic. Diagnostic segment comprising of SPECT and PET radiopharmaceuticals was dominated with about 83% share in 2012 [19]. The lion's share of the SPECT market is taken up by Tc-99m, whereas the PET market is dominated by F-18FDG isotope. Furthermore, the

1982- Local Focus	1992-Reginal Focus	2002-Global Focus
Manufacturing plants report to local affiliates	Plants have regional reporting structure	Plants have global reporting structure by network
Mainly local production	Regional production	Global production-many nodes
Presence sites in Europe as well as Intercontinental	Some presence benefits in Europe as well as intercontinental	Reducing presence benefits in Europe less tied to specific products
Local launches of non- global products	Few global product launches	Many global product launches with global processes
Optimize local site to meet affiliate need	Optimize regional capacity	Optimize global network capacity
Cost focus	Cost focus	Revenue generation focus

Driven by: Decreased trade barriers; Increased regulatory standards and manufacturing costs, pricing pressures, speed to market

Table 1: Shifted Business Focus of Elli Lily [6].

Figure 3: Elli Lily's supply chain [6].

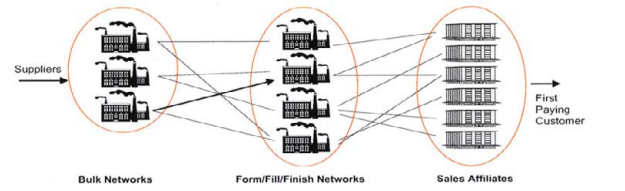

Figure 4: Elli lily's manufacturing network [6].

PET market will witness a double-digit growth during the forecasted period [20]. The therapeutic segment contributes only 10% to the global radiopharmaceutical market and I-131 is considered as the gold standard for various oncology treatments in a combined therapy.

In addition to the most preferred isotopes (such as Tc-99m and F-18), significant growth is witnessed for Rb-82 and Ga-68 in diagnostic market and Y-90, Lu-177 and Ra-223 in therapy radioisotopes market. Exhaustive pipeline analysis shows that while coronary heart disease, Alzheimer's disease, breast cancer, and bone metastasis will be the driver of the diagnostic radiopharmaceuticals market, lymphoma, prostate cancer, bone metastasis, and hepatocellular carcinoma shape the therapeutic segment [20].

Radiopharmaceutical industry, considered as a sub-branch of pharma industry, has a unique structure. Some other structural complexities that can be added to this unique structure are: 1) when the profiles of industry players are considered; except for two major players of the industry, which are also players in pharmaceutical industry (Schering and Covidien); it is observed that the other players are also medical device manufacturers (like Siemens, GE, Iba, AAA) which are not familiar with the pharma-business model principles.

2) Due to the radioactive nature of this group, radiopharmaceuticals have been produced as magisterial product since 2000 and used locally for years. The licensing of these products was enforced in 2000. In the same year, licensing and Good Manufacturing Practice (GMP) compliance of radiopharmaceutical production facilities has also been obligated. Today marketing authorization is not required for the local usage of some of these products. This makes the regulatory authorities, which are active agents in shaping business strategies in pharmaceutical industry, become new stakeholders of the industry.

3) As a result of generally having short-lived radioisotopes, measured in minutes rather than days, most radiopharmaceutical products have short shelf life. This prompts radiopharmacies to produce more radiopharmaceutical than often needed, which on the financial side further increases the costs. On the operational side, however, this means no inventory, forecasting uncertainty, supply to daily-based demand, quick respond to demand changes.

4) Because of being radioactive in nature, the radiation protection requirements should be followed from production to delivery stage. This, in turn, further increases the financial and operational costs.

The biggest challenge in radiopharmaceutical industry is bearing the R&D costs. The cost and duration of diagnostic radiopharmaceuticals development is $ 100-200 million and 8-10 yrs, relative to pharmaceuticals, for which $600 million to $1.2 billion over 10-12 yrs [21]. Compared to multibillion annual sales, the annual sales of best-selling imaging radiopharmaceuticals are in approximately $ 400 million range [21]. When considering the most commonly used FDA-approved 3 radiopharmaceuticals developed between 1980-1990, current R and D costs expected to be supported by revenue from these products. Here is the main problem: with reimbursement rates of $100– $200 per dose, the necessary revenue to cover these costs may be possible with the use of 1 million doses of these products.

As consequence of these structural complexities and challenges, the basic challenges that occur in supply chain management are: reliable supply of radiopharmaceuticals, management of mostly daily-based demands, and quick response to changes in demands, improving access and enhancing safety.

Most well-known supply chain management success story in radiopharma market emerged during Molybdenum-99 (Mo-99) shortage. Today, over 100 different nuclear medicine applications exist, about 70% of which rely on Mo-99. Mo-99 is one key medical radioisotope largely used in the diagnosis of heart disease and cancer. Mo-99, the parent nuclide of technetium-99m (Tc-99m), is a reactor-produced radioisotope. A typical Mo-99 supply chain is illustrated in (Figure 5)[22].

In 2009 Chalk River, one of the major manufacturing sites of Mo-99, was shut down because of leak in reactor and scheduled to close in 2016. In 2010 Pettern, another important site, was shut down for planned maintenance. Between 2010 – 2013 period, there were only two open manufacturing sites of Mo-99. Hence, worldwide a Mo-99 crisis was seen. Two big radiopharmaceutical distributors were the winner during this shortage. Ameliorated activities that were announced as these companies' short-time, mid-term and long-term strategies were: 1) having supplier agreement with both manufacturers, reactor scheduling and communications, 2) improved communication with medical community, industry and specialist societies, 3) helping medical community to publish guidance documents reduced patient dose and reallocating patients to other tests, 4) alternative radiopharmaceuticals ((18F) NaF, for bone metastases) and alternative production methods (by cyclotron, Linacs/Elinacs), 5) Infrastructural changes in reactors as a) Expanding number of reactors providing irradiation services for processing facilities b) Replacement of aged reactors with a new generation of reactors c) Replacement of highly-enriched uranium (HEU) with low enriched uranium (LEU) [23].

During this period, two new radiopharmaceuticals that were approved were (18F) NaF (licensed in 2012 in EU and USA), and LEU TecneLite(licensed in 2010 in USA) were. Although many important steps were taken, this Mo-99 supply chain will continue to remain fragile because its production still relies on the same five aged production reactors. Considering the aging condition of global reactors and the uncertain sustainability of their production, long-term projects and/or alternative technologies are still required to address the growing demand for technetium-99m-based diagnosis and therapy. However, as they require sizable investment, these projects need to be supplied by the governments.

Second supply chain management success story worth to discuss is the Cardinal Health-TATA Counsultancy (TCS) collaboration. The goal was to produce and deliver high-value, short-shelf-life products

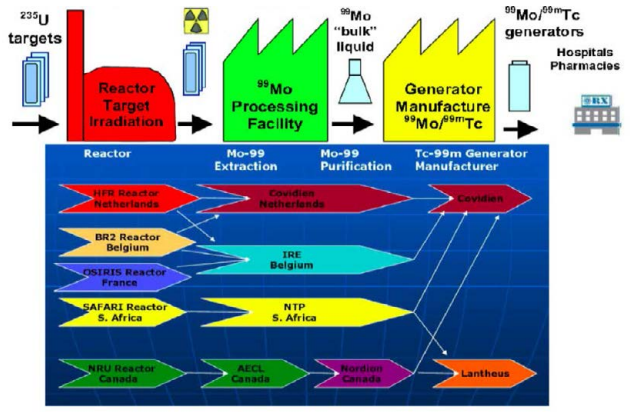

Figure 5: Supply chain of Mo-99/Tc-99m [23].

throughout the supply chain in a more efficient and timely manner. Mr. Claunch, the Vice President, defines this collaboration as [24] "*Real-time visibility into our radiopharmaceutical prescriptions allows us to deliver safer products rapidly, at less cost. TCS helped us successfully implement a real-time radiopharmacy system that improves customer satisfaction and strengthens our bottom line*"

In addition to being a player as a distributor in pharmaceutical industry in USA, Cardinal Health is a leading provider of unit-dose radiopharmaceuticals in the country and has a national network of more than 140 nuclear pharmacies that prepare and deliver more than 12 million unit-dose radiopharmaceuticals annually. Though having a huge experience as a distributor in Pharma sector, Cardinal Health experienced important challenges in nuclear pharmacy service business. As determined by TCS, Cardinal Health's decentralized IT systems and manual process was 1) unable to accommodate last-minutes changes or track deliveries in real time, 2) unable to pinpoint the exact time when radiopharmacies should procure highly expensive and short half-life radioactive materials to ensure the proper patient dosages, and 3) unable to monitor and control revenue and vendor payments [24].

TCS' solution was to deliver direct visibility into orders, inventory, financial information and the location of orders as they tracked across the supply chain to radiopharmacy customers. Here are the successive results of this agreement [24]:

From the operational aspect:

· By replacing several manual processes with electronic capture-proof processes, Cardinal Health reduced manual error across the supply chain, which dramatically lessened incorrect orders.

· This increased operational efficiency eliminates the need for prior-day setup work. It not only simplifies the production cycle, but also allows for changes to dosages up until the time the prescription is created –which have also eliminated waste and dramatically reduced costs.

· Using geographical route-tracing intelligence, Cardinal Health can now optimize delivery routes used by drivers and receive proper check-offs along the process using each driver's tablet computer. These steps not only reduce the need for driver overtime, but they speed the time between dosage creation and delivery. Less radioisotope decay allows Cardinal Health to mix less potent dosages, which further drives cost savings.

From the financial aspect;

· Delivered real-time visibility into financial performance.

· Reduced time through centralized customer billing, using centralized vendor invoices with three-way match (purchase order, goods receipt, and vendor invoice) and end-of-month accounting processes.

· More standardized pricing algorithm

Future perspective: Pharmaceutical companies shifted their business strategies from local to global in last decade. According to the UPS 2012 "Pain in the Chain Survey," 83% of healthcare companies surveyed rank tapping into new global markets as a top strategy for the next three to five years [25]. As a result of these new strategies, companies tend to build network communities consisting of various companies specialized in different core competencies. Correspondingly, the function of supply chain management evolved from management of logistic operations to orchestration of value chain. This turned supply chain management into the core component of business strategy. To our belief, this "network model' will not only help to gather various players in different segments, but also accelerate the cumulation of high value know-how in pharmaceutical industry. Today's major pharmaceutical companies will play a role as a network integrator.

Inspite of the fact that radiopharma industry of which regulatory bases are formed relatively later than pharma industry, the steps taken are quite significant. Especially, the FDA's recognition of medical imaging biomarkers as critical to medical product development in the "Critical Path Initiative" report (2004) [26] has lead to the use of radiopharmaceuticals in drug development. This caused many large pharmaceutical companies to invest in radiopharma sector. Obviously, the know-how that these new players will bring into the radiopharma industry will reshape the supply chain management.

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