Active Pharmaceuticals Ingredients Suppliers’ role to improve the availability of Antibiotics in Sweden through the supply chain

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Abstract

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The rise of antibiotic resistance and the difficulty in the procurement of active pharmaceutical ingredients (APIs) used in the manufacturing reduce the availability of antibiotics in Sweden. The main objective of the study is to explore the APIs market in India and analyze the major suppliers to support the stable production of antibiotics which suffer from shortage in the Swedish market.

This research is concerned with the API supply stage concerning the rest of the antibiotic supply chain. It includes the structure of the local industries and the strategies adopted by the leading players. In this regard, the relevant literature on pharmaceutical supply chains and strategy and on other initiatives to combat antibiotic resistance are referred with the motive to establish a theoretical base for the practical findings.

The interviews with the supply manager of major API suppliers have conducted in India and various reports on APIs suppliers are studied. The challenges in the supply and export of APIs are explained in the interviews. The current players and government initiatives to promote the export of APIs help to understand both internal and external problems related to the export of APIs.

The thesis is concluded with the recommendations of Indian APIs producers that can be considered by the pharmaceutical companies producing antibiotics to establish a reliable and robust supply chain between them.
Popular Scientific Summary

The shortage of antibiotics is a global problem, and the most affected countries have started taking initiatives to tackle the problem by working with pharmaceutical companies (Svarm, 2018). It is essential to study each node of the complex network of the pharmaceutical supply chain to deal with a shortage of antibiotics. This study explores the potential of existing Indian APIs suppliers that comes at the APIs supplier’s node in the supply chain after the procurement of raw material and intermediates.

To understand the importance of efficient APIs suppliers in the unavailability of antibiotics, the literature related to emerging antibiotics resistance, supply chain models in the pharmaceutical industry have been reviewed. Two books on Porter's five forces model and articles on the use of five forces in other industries are used for analyzing the pharmaceutical market. Primary data was collected to get a deep understanding of Indian APIs, and secondary data such as government reports and articles on the APIs market in India were analyzed.

The motive of the research is to deliver information related to trusted APIs suppliers from India for the antibiotics which suffered shortages in the Swedish. The list of the APIs supplier’s strategies with their offerings might be useful for researchers working in the pharmaceutical industry related to sourcing of APIs. The knowledge related to the APIs producers and the environment in which they operate can facilitate in building an efficient sourcing strategy, ensuring timely and efficient availability of APIs.
Acknowledgment

This Master Thesis has been written in collaboration with Uppsala University. The work has been done by Meenu Choudhary and Abdul Rehman Abbasi with the help of some supply managers from Indian pharmaceutical companies for empirical studies.

We want to express our gratitude to our supervisor, Ines Julia Khadri, a Ph.D. student at the Department of Engineering Sciences, Industrial Engineering & Management at Uppsala University and subject reader, Dr. Serder Temiz, visiting faculty at Department of Engineering Sciences, Industrial Engineering & Management in Uppsala University. They helped us throughout our thesis very extensively and guided us towards academic writing.

We want to thank the Department of Industrial Engineering & Management at Uppsala University involving all the professors who taught us our courses at this University. It is thanks to my education here that I was able to write this degree project. We want to thank our fellow students, who shared their valuable feedback on our thesis work throughout the journey. At last, we would like to thank all the people who worked or working in PLATINEA project to share the other aspects of the project.
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Abbreviations

API – Active Pharmaceutical Ingredients
AMR – Anti-microbial resistance
BP – Big Pharma
CDSCO - The Central Drugs Standard Control Organization
EDQM - The European Directorate for the Quality of Medicines & HealthCare
FDA - Food and Drug Administration
GMP – Good manufacturing practice
PLATINEA - Plattform för Innovation av Existerande Antibiotika
PCB - Polychlorinated biphenyl
USFDA – The United States Food and Drug Administration
WHO - World Health Organization
1. Introduction

In 1928, Sir Alexander Fleming laid the foundation of a new era of antibiotics by discovering penicillin. The antibiotics not only transformed the way medicine is practiced but also saved millions of lives by successfully controlling bacterial infections (Sengupta et al. 2013). The antibiotic resistance is now rising and will have a devastating effect on humans with the increase in frequency and scope of lethal diseases (Carolyn et al. 2014).

In 2017, insufficient availability of antibiotics was observed in Sweden, and this concerns the doctors as it changes the available treatment options and affects the safety of patients. Children are especially more vulnerable to the effects of shortages in antibiotics as they require a specific type of antibiotics with a few alternatives (Svarm, 2017). Developing new antibiotics is one of the solutions to combat antibiotic resistance, but economic and regulatory obstacles triggered the pharmaceutical companies to abandon the field of antibiotics (Ventola, 2015).

For many antibiotics, the supply chain relies on a handful of suppliers of Active Pharmaceutical Ingredients (APIs) in India and China. Factors such as slim margins on antibiotics demand uncertainty and the costly R&D leave pharmaceutical companies with low incentives to develop and manufacture antibiotics. The antibiotic supply chain is fragile and at the risk of collapsing, which can potentially cause the shortage of antibiotics resulting in an outbreak of diseases. Thus, the supply chain should be strengthened to meet the demand for antibiotics by ensuring enough and uninterrupted supply through proper distribution channels and demand planning. (Cogan et al. 2018).

The project PLATINEA (Plattform för Innovation av Existerande Antibiotika) is a collaborative platform that works to address many issues related to a shortage of antibiotics in Sweden. One of the problems is to identify the issues in the supply chain of antibiotics (Cicek et al., 2019).

The study contributes to the knowledge of existing and potential Indian Active Pharmaceutical Ingredients (APIs) manufacturers in the availability of antibiotics in Sweden based on the empirical research of primary and secondary data.


1.1 Objective and Research Question

To tackle the problem of shortage, stockouts, and scarcity of antibiotics in Sweden, it is crucial to increase the visibility and accountability in the fragmented supply chain system. There is a weak linkage among a few large companies and many small APIs suppliers in Asian countries, specifically India. (Cogan et al., 2018)

The objective is to contribute the knowledge of Indian APIs manufacturers in the antibiotic supply chain. The study includes the unavailable antibiotics in Sweden and their potential APIs suppliers from India. It analyses the Indian API supplier’s strategies regarding their supply for the Swedish market for antibiotics. The focus is on the specific APIs concerned with the production of antibiotics that are in shortage.

The thesis aims to address the following key research questions:

1- Who are the APIs manufacturers, and what are their strategies in regards to the APIs supply for the global markets?
   a) Who are the major pharmaceutical players in India and their export strategies?
   b) What are the competitive forces in the pharmaceutical industry based on Porter's five forces analysis?
   c) Who are the Indian APIs manufacturers exporting APIs, that are scarce in Sweden, to the global market?

2- What are the APIs company-specific business strategies based on their historical development?

1.2 Current state of research and contribution of this study

Current researches mainly uncover the complex and fragmented supply chain in the pharmaceutical industry (Cogan et al., 2018). Many studies are attempted to understand the strategic outsourcing done by many big players in the pharmaceutical industry from different perspectives (Huq et al., 2016).
The research done on the pharmaceutical supply chain depicts a fragmented supply chain. The issues regarding excessive use of antibiotics which leads to the emergence of antibiotics resistance have been studied. There is a clear and concentrated dependence on very few actors in the procurement of APIs which results in a variety of supply problems. The supply inefficiencies are due to a variety of reasons such as the problems in the manufacturing processes, quality and regulatory issues, pressures on margins, and many more. (Cogan et al., 2018)

All these contributions from different researchers give an overall view of the complete supply chain in the pharmaceutical industry. However, no relevant research has come to notice, which focuses explicitly on the connection between the Indian APIs producers and the pharmaceutical companies producing antibiotics in Sweden. The study focuses on business operations of the leading Indian APIs producers and their strategies to export in global markets.
2. Background

To understand the root cause of the shortage of antibiotics and the role of the efficient supply chain in pharmaceuticals, the study on the unavailability of antibiotics in Sweden and different supply chain models would help to investigate the various associated aspects of the problem.

2.1 Shortage and unavailability of antibiotics

There is a strong connection between emerging antibiotics resistance and the shortage of antibiotics in Sweden (Cogan et al., 2018). The availability of antibiotics or any other drug depends on the supply chain. The supply of antibiotics goes through several actors that successively includes pharmaceutical companies, wholesalers, and healthcare center. The pharmaceutical companies have a little willingness to invest in developing new antibiotics and rebuild the weak supply chains to combat the increasing cases of antibiotics resistance (Cogan et al., 2018).

Taking into consideration the small size of the Swedish market, pharmaceutical companies find it unattractive to register antibiotics and tackle the shortage of antibiotics. It is also very unpredictable to assess which antibiotics will be insufficient to cater to the need of healthcare centers in Sweden (PSHA, 2017). The availability depends on factors such as demand planning, uninterrupted supply, and proper distribution (Cogan et al., 2018). The Swedish government has taken the initiative to monitor the availability of old antibiotics through an online platform (PSHA, 2017). “The occurrence of out of stocks situation is monitored using information from the MPA and Apoteket’s website on out-of-stock notes.” (PSHA, 2017, pg. 20). The platform is primarily built for stock and inventory management of antibiotics.

One of the causes of the shortage of antibiotics is the unstable business model. The model is based on a slim margin on antibiotics and the high purchasing power of government cutting the margins and sales volume due to controlled usage because of antibiotic resistance (Cogan et al., 2018).

2.2 APIs Supply Chain in the Pharmaceuticals Industry

The pharmaceuticals supply chain is very complex and interdependent and involves many stakeholders, processes, and resources to provide high-quality medicines. International
coordination and collaboration from different stakeholders, especially the government agencies, will be required to strengthen the supply chain. The timely availability of the active pharmaceutical ingredients is critical to smoothly run the manufacturing process of the crucial drugs to ensure their availability in the market. The global supply chain is affected by multiple numbers of factors as the geographical locations of the transacting partners differ in a variety of ways. (Cogan et al., 2018)

Many companies in Eastern Europe find more convenient places with relatively positive factors such as regulations, cheap and skilled labor, and cultural similarities such as knowledge of languages (Huq et al., 2016). For Asia, the primary focus is on scale and cost efficiency by the creation of economies of scale because of the availability of the massive skilled human resource (Huq et al., 2016).

![The Pharmaceutical Supply Chain](image)

*Figure 1- The Pharmaceutical Supply Chain (Lonaeus, 2016)*
Based on Fahain’s case study, there are three supply chain configurations: insource nearshore, outsource nearshore, and outsource offshore. The assumptions are that supply chain models are for European countries, and the raw material is outsourced from China. (Huq et al., 2016)

Near insourcing occurs when most of the activities take place in the country of origin. The raw material is outsourced from China and other countries, and then it is used to manufacture APIs and final finished products. (Huq et al., 2016)

In nearshore outsourcing, some of the activities are outsourced to eastern European countries due to low labor costs and a highly skilled population. The API manufacturing and finished product are now outsourced to Eastern Europe. Eastern Europe constitutes Belarus, Bulgaria, the Czech Republic, Poland, Russia, Slovakia, Ukraine, Romania, Hungary, and Moldova. (Huq et al., 2016)

In offshore outsourcing, a part of value chain is transferred to the remote location or countries for factors such as low labor cost, fast registration of new drugs. The type of supply chain configuration used depends upon the type of drug. For instance, companies prefer to have control over manufacturing when it comes to core drugs and willing to outsource non-drug manufacturing. (Huq et al., 2016)

Outsourcing strategy, employed by most European pharmaceutical companies including companies in Sweden, resulted in the creation of complex supply chain structures. These structures have several dependency constraints which affect the whole ecosystem of the drug market (Huq et al., 2016).

According to the Swedish Public Health Agency (folkhälsomyndigheten) report, the low sales of antibiotics are the result of the restrictive use of antibiotics resulting in small profits for the pharmaceutical companies producing and selling these antibiotics.

Local manufacturing of APIs in Sweden might not be a cost-effective option for pharmaceutical companies because the market in Sweden is small and has a limited purchasing power of the pharmaceuticals (Lonaeus, 2016). So, it is vital to maintain the supply and buffer stocks to cater to a sudden surge in demand for antibiotics. (Cogan, et al. 2018). For example, “Mylan maintains Vendor Managed Inventory (VMI) to cater to emergency orders and stockouts in various
countries through a partnership with the Global Fund” (Cogan et al., 2018, pg. 14). For pharmaceutical companies, it is also important to have multiple suppliers to avoid dependency.

Quality can be controlled when the companies have an in-house production facility of APIs. Quality assurance might become an issue when companies plan for outsourcing APIs. Engaging with suppliers for good manufacturing practice might ensure the companies for quality products. The engagement can be done in terms of training and investment in infrastructure (Cogan et al., 2018). The access to company details in the public procurement process might be a hurdle for the companies to participate in the bidding process. The competition is cut-throat, and the vulnerability of the company's intellectual property might be disastrous. (Lonaeus, 2016).
3. Literature Review

In the modern world, the race to deliver solutions faster and cheaper is driving businesses to explore new markets for procurement, production, and sales of their products. The following literature review explains the research regarding the general problem of antibiotic resistance and difficulties in strategy, competitive advantage, outsourcing, and supply chains.

To understand the root of the problem of growing antibiotics resistance, Peter et al. (2017) explain the sustainability point of view and relates AMR (antimicrobial resistance) to other environmental issues. It is important to take it as a global sustainability challenge to curtail antibiotic resistance and overuse of the antibiotics. The same research further explains that the reliance on drug innovation and drug pipeline to deliver new drugs delay the problem, which in the future can rise to practically irreversible levels.

Smith et al. (2002) explains that the responsibility related to health care solely remains national, but due to the increase in globalization, the problem of AMR is no longer controlled by individual countries. It requires a global response to curb antibiotic resistance. In their research, the current national and international responses are assessed, and strategies are proposed to improve the collective response to antibiotic resistance. A global collective action, along with the appropriate surveillance, is required with the focus on containment to avoid further emergence of antibiotic resistance. It is suggested to gather data around growth, transmission, and direction of travel which will allow measurement of the impact of the response measures to tackle the problem. Strategy to have a collective plan to initiate research and development on new antimicrobials and other therapies along with encouraging appropriate and rational use of antibiotics is explained as the way to tackle the problem. Compliance of countries across issues related to both economic and legal dimensions is also very critical in achieving across the board control of antibiotic resistance.

Fair et al. (2014) puts forward the case of antibiotic resistance with extensive details of the profiles of bacterial species and the adoption of approaches by the scientists in the pursuit of new antimicrobial agents. The research is delivered while taking into account the related factors of economic impact, degree, and type of resistance, morbidity and mortality rates and the source of infections. The research explains the reduced investments from the large pharmaceutical groups.
in antibiotic research and development due to the low return on investment. The reason is that the antibiotics are usually kept in reserve as compared with other drugs to treat chronic ailments. In contrast to these, other factors that boost antibiotic resistance are the lack of public awareness, misuse of antibiotics through over-prescription, and misuse by the food industry.

Gwynn et al. (2010) explain the high level of innovation gape in the antibiotics and the emerging bacterial species and suggests collective response from the public and private entities working to eradicate antibiotic resistance in the form of creating economic incentives in the way of discovery and development of antibiotics. Among the key factors of incentives and regulatory environment, the technology factor is stressed as the barrier to the development of new drugs and overcoming the associated challenges.

Huq's (2016) research on the disturbance factors in the pharmaceutical supply chain has an extensive view of the overall supply chain with a focus on the problems in the supply chain with configurations of supply chain arising from the strategies of the big pharmaceutical players. Different types of sourcing and the disturbance factors are extensively discussed with data collected over a period to identify top issues occurring due to this geographical spread of operations. The article delivers a clear understanding of the concepts in the sourcing with factual data to provide managerial implications.

Koh's (2003) research concerning the problem of counterfeiting also explains the risk related to outsourcing with the changing regulatory requirements making it complicated for both the manufacturers and the distributors. The research covers the explanation of the points in the whole pharmaceutical supply chain and the accountability procedures in steps to secure the pharmaceutical supply chain. This emerging need for accountability in the pharmaceutical supply chain is connected to technology inclusion which can increase the transparency of the whole procedure.

Kapoor (2018) considers supply chain management in the pharmaceutical industry as the renovation factor allowing the organization to make better use of assets and resources with the motive to increase profits and value. The research identifies the main issues in the pharmaceutical supply chain in the Asian regions such as counterfeiting, unfavorable reaction, issues related to entities in the supply chain, manufacturing issues, retailer issues, transportation issues, storing and warehousing, raw materials supplier issues. All the mentioned issues give rise to the series of
implications for the whole industry with the stringent regulatory requirements and the other requirements for various points in the supply chain ranging from reforms in the logistical set up to the inclusion of technology-based solutions to increase visibility and transparency in the whole supply chain.

Mahajan (2014) explores the emergence of the pharmaceutical industry in India with an analysis of the exports and the associated growth rates. India is emerging as a major exporter of formulations and bulk chemicals with growing R&D facilities to capture an even greater share in the market.

The discovery of penicillin and the evolution of antibiotics in the healthcare industry has transformed the way medicine is practiced. But soon the pathogens have developed the resistance to antibiotics. Many studies have been done to understand the intricacies between the use of antibiotics and the emergence of antibiotics resistance. (Sengupta et al., 2013). It has been determined that increasing AMR (antimicrobial resistance) is the result of the widespread use of antibiotics, the presence of antibiotics in the environment through various channels, and the unnecessary use of antibiotics. The preventive measures such as research on new antibiotics and education programs to educate the healthcare world are proposed to deal with the problem of AMR. (Carolyn et al. 2014)

The factors for shortage of antibiotics are the emergence of antibiotic resistance, no planning for stockouts and forecasting, the disinterest of pharmaceutical companies to invest in developing new medicines and the slim margins on the generic antibiotics (Cogan et al., 2018).

To understand the role that APIs suppliers can play in pharmaceutical supply chains. It is crucial to understand the issues associated with antibiotics availability and other drivers such as government and pharmaceutical companies' roles (Cogan et al., 2018). The case study of other European countries dealing with the shortage of antibiotics gives some insight on possible pathways to encounter this problem (Berger, 2018). The three supply chain configurations are used by European pharmaceutical companies based on an empirical study on supply chain management and related cause of disturbance and probable mitigation process. It is challenging to come up with a supply chain configuration that suits each drug and every company (Huq et al., 2016). The government is working on different economic models that can be used to cater to the problem of shortage of antibiotics in Sweden (PHAS, 2017).
To shape the strategy for APIs manufacturing, the companies consider the factors that drive the pharmaceuticals market. The analysis of Porter’s five forces for the pharmaceutical industry can help to position the company in a strategic domain (Porter, 1996). The pharmaceutical industry is very dynamic and changes with drug regulation and innovation of new drugs. The companies revise the strategic thinking and planning to deal with new challenges and focus on developing a competitive advantage by analyzing Porter’s five forces (Kasapi & Mihiotis, 2011). The analysis of Porter’s five forces model in the Saudi Pharmaceutical industry reveals that industry has a favorable advantage for suppliers, buyers, and rivalry among competitors but lacks a favor to the threat of substitutes and threat of new entrants (Hassan & Arfaz, 2016).

The supply chain in the pharmaceutical industry is very complex, and it is essential to analyze the different stakeholders in the supply chain (Kapoor et al. 2018). The study of API manufacturers in India and their portfolio provide insight into factors affecting the import of APIs in the global market (ASSOCHAM, 2016). The global trend in pharmaceutical and government regulation do impact the Indian Pharmaceutical industry growth and its role in the global market (EXIM Bank Report, 2016).

The performance of Indian pharmaceutical companies and their role in the global market can be used for future growth strategies. There are many pharmaceutical companies in India, so it is vital to understand the portfolio of each one of them and their contribution to the industry (Dun & Bradstreet India, 2016). The selection of API manufacturers in India is based on the quality of products. The selection process includes risk assessment, specifications, analytical results, document review observations, and inspection results (Mallu et al., 2015). The Contract Research and Manufacturing Services (CRAMS) options also contribute to the growth of the pharmaceutical market in India (LSIT, 2016).
4. **Theory**

The basis of Porter's five forces is industrial organization theory. The industrial organization theory assumes that the attractiveness of an industry is determined by a market structure that affects the players in the market (Raible, 2013). The market structure influences the strategic behavior of organizations, and market success depends upon the competitive strategies. Thus, the success of the organization is indirectly affected by market structure.

Porter's five forces play an integral part in building a strategy. Understanding the five forces not only enhances the strategy but also influences the profitability of the organization (Porter, 1996). Apart from competition among the existing rivals, Porter's Five Forces model identifies another four forces: Bargaining power of suppliers, Bargaining power of buyers, Threat of substitutes and Threat of new entrants to characterize the intensity of competition in the industry (Porter, 1979). The competition with existing rivals, potential entrants, and substitute are three forces in horizontal competition and power of suppliers and buyers are in vertical competition (Grant, 2010). The analysis can help the organization to set a position in the market to get a competitive advantage. Porter's five forces individual impact and their collective effect change with the socio-economic environment and government policies (Mohapatra, 2012).

In this fast-paced Information technology era, there is a great access to infinite information and data about the customers, suppliers, and competitors. In the porter five forces, IT is not involved because traditionally, it is considered a tool to implement changes. But now the time is changing, and customers have more access to information and greater access to various products available in the market (Dälken, 2014).

In "Rivalry Among Existing Competitors, there are many forms of competition, for example, "price discounting, new product introductions, advertising campaigns, and service improvements" (Porter, 2008, pg. 32). The level of rivalry influences the profitability of the business, and it depends on the "intensity with which companies compete and on the basis on which they compete" (Porter, 2008, pg. 32). The industrial growth rate, fixed cost, number of firms. Switching costs and exit barriers can influence the rivalry among existing competitors. (Hubbard & Beamish, 2011; Slater & Olson, 2002; Johnson et al., 2008).
Figure 2 - Porter Five Forces Model

The pharmaceutical industry is a highly competitive and aggressive market. Increased competitiveness, massive investment in R&D, quick development of generic drugs are some characteristics that can help to analyze Porter FFM. Every company is trying its level best to stay ahead in the market. The pharmaceutical market is driven by innovation, intellectual properties (IPs), and patents. The government plays an essential role in the testing of developed drugs and regulating the price in the market. (Kasapi & Mihiotis, 2011)

Competition in some industries is driven by pushing the pricing down, but in pharmaceuticals, it is driven by innovation. There are four factors that can be considered while analyzing the rivalry in the market. The concentration of the seller, which means the lesser the number of the dominant player in the market, lesser will be the focus on pushing down the pricing. In such a scenario, the company's focus is on marketing, advertising, and product development. Diversity of competition and product differentiation are some of the other factors that affect rivalry in the market. (Grant, 2010)

Substitute products can limit the profit potential by defining a cap for the prices of the products already available in the market (Porter, 1979). According to Hubbard and Beamish (2011), there
are other factors such as switching costs and buyer's loyalty towards a particular brand that influences the threat of substitutes.

The customer's willingness to pay the price of goods depends upon the availability of a substitute in the market. Substitute products affect the profit of the company having a patent (Hassan & Arfaz, 2016). The existence of close alternatives at a lower price attracts the customer to switch to the product. The customer also considers the performance of the product, which is sometimes difficult to evaluate. Generic drugs are usually the main substitute produced by pharmaceutical companies. (Barney, 2006). It is debatable whether to consider generic drugs as substitutes or rivalry (Kasapi & Mihiotis, 2011).

Return on investment in any industry drives more companies to enter the market. "New entrants to an industry bring new capacity, the desire to gain market share, and often substantial resources" (Porter, 1979, pg. 138). The existence of a high entry barrier limits the industry and influences' Rivalry Among Existing Competitors' (Johnson et al., 2008). The entrance of a new company in the market gains some shares of the market and leaves the buyers with more purchasing options. Higher the entry barrier, greater will be the benefit to the existing companies in the market for business. "The height of barriers to entry has been found consistently to be the most significant predictor of industry profitability" (Rothaermel, 2008, pg. 215). Economic of scale, product differentiation, capital requirements, cost disadvantage, are some contributing factors to entry barriers.

Capital requirement to enter into the new business market, the role of economy of scale, product differentiation, access to the channel of distribution and government and legal barriers are some of the factors that challenge the new entrant into the market. (Grant, 2010). The threat of new entrants is very low as it requires a high initial investment, and developing a new drug requires years of R&D and clinical trials. The pharmaceutical industry is highly regulated by the Food and Drug Administration, and the standards are stringent. Furthermore, the patent of any drug lasts for 20 years, which discourages the new entrant from trying to enter the generic market (Kasapi & Mihiotis, 2011).

If the buyers have a high purchasing power, then they can influence the price and quality of the product and sometimes compel the companies to provide extra services. This affects the
profitability of the industry. The Bargaining Power of Buyer is high when there are a large number of buyers, and when the cost of switching is low (Slater & Olson, 2002).

There are two types of markets considering the position of buyers in the supply chain, input, and output. In the input, the company purchases the raw material and other components, and in the output market, the company sells the products and services to the end consumers. The buyer's price sensitivity depends upon the importance of a product, the intensity of competition among the buyers, and the criticality of the performance of a product. Not only that, the bargaining power of suppliers get affected by the size and concentration of buyers and the information about the buyer's pricing to its customers. (Grant, 2010).

In the pharmaceutical industry, buyers do not hold higher bargaining power than pharmaceutical companies. Doctors, patients, hospitals, drug stores, and pharmacists are the buyers in the pharmaceutical industry. In case of generic drugs, the patient might prefer low-cost medicine, but big hospitals can pressure pharmaceutical companies at lower prices. In case of patented drugs, pharmaceutical companies have a monopoly on pricing until the patent get expired. (Kasapi & Mihiotis, 2011).

Bargaining Power of Supplier is defined as the risk associated with the supplier based on the dependency of the company on it. "Powerful suppliers can thereby squeeze profitability out of an industry unable to recover cost increases in its prices" (Porter, 1979, pg. 140). The bargaining power of suppliers depends upon the size of the supplier, the number of suppliers, and the availability of alternative customers (Slater & Olson, 2002).

The bargaining power of suppliers in the pharmaceutical industry is low as the raw material, semi-finished products, and components are supplied by small companies to large companies. Suppliers' unions boost the bargaining power of suppliers (Grant, 2010). The supplier could be a provider of raw material, intermediates, manufacturing and production plants, marketing offices, local co-marketing partners who supply products. It is not easy to change the suppliers easily as each supplier does hold a certain level of power. But still, the bargaining power of suppliers is not significant to pharmaceuticals companies. (Kasapi & Mihiotis, 2011).
The analysis of Porter's five forces gives a business strategist an understanding of the profitability and attractiveness of the industry (Johnson et al., 2008). The model provides the opportunity to examine and evaluate the complex interactions of competitors in an industry in a structured way (Porter, 1979).

Although the Porter Five Forces model is one of the most known and widely spread management models in practice, there is some criticism as well in recent years (Dulčić et al., 2012). According to Thyrlby (1998), FFM is static and does not consider the time. Nowadays, the market is highly dynamic, which demands new models. Taking time as one of the dimensions, the strategist can consider trends and changing environment while building the strategy. Furthermore, the model does not assess the resources and capabilities of a company, which are also relevant for analyzing the overall profitability (Rivard et al., 2006).
5. Methodology

The research must follow a clear methodology to establish logical answers to the research questions. The research includes empirical studies of both primary and secondary data. The study used Porter's five forces model to understand the Indian APIs market. The analysis is to identify existing APIs manufacturers in India based on available scientific journals, articles, and companies' annual reports. The empirical data is collected through interviews with the supply chain managers of APIs manufacturers in India.

The justification for the chosen approaches is provided, which are used to full fill the objectives of the thesis. Also, the limitations of the applied methods are explained.

5.1 Research Framework

The research is qualitative. In the first phase, the task by careful analysis of all the available information in the form of publications from different researchers. In this regard, various books, journal articles were used to interpret the background knowledge and to establish a clear motive for the research. The methodology is first to review all the relevant articles and identify the key questions that can be addressed while conducting the semi-structured interview. The related articles on antibiotics, antibiotics resistance, and its shortage in Sweden, the supply chain in the pharmaceutical industry and the use of Porter’s five forces model in the pharmaceutical industry were identified through secondary data searches. The multiple sources strengthen the research as more information with different perspectives can be integrated into the study.

The methodology follows two phases; the first phase focused on reviewing all the relevant information sources related to the research questions and the second phase is to the identification of the essential questions that need to be answered to address the research objective. The structured and semi-structured interviews are conducted based on these questions.

It is crucial to be clear and explicit about the research method and analysis to avoid the subjectivity in qualitative analysis (Greener, 2008). There are many qualitative methods to carry out the research.


5.2 Data Collection Methods

There are many methods to collect data such as interviewing and questionnaires. Some of the methods entail the structured approach, which means first to design research instruments to get what needs to be uncovered. The structured interview is an example of such tools, and it is the kind of interview with designed questions used in a survey investigation (Bryman, 2012).

5.2.1 Data Collection Method

Conducting survey research by questionnaires and interviews will be very time-consuming. We have utilized the secondary data for this study. The data from government, industry, and organizations may be used by the researcher rather than collecting the data by themselves (Bryman, 2012).

Secondary analysis is the analysis of data that is not collected by researchers but analyzed by the researchers. The secondary analysis involves either the analysis of quantitative data or qualitative data. The secondary data collected by companies and government is used in the research and analysis (Bryman, 2012).

The research interview is a prominent data collection strategy in qualitative research. The structured interviews, semi-structured interviews, and open interviews are conducted based on the type of research and available resources. The semi-structured interview refers to the interview in which the interviewer has a series of predefined questions but the researcher can still leave the questions open if new unexpected issues are raised during the interview (Bryman, 2012).

**Ethical considerations**

Ethical issues considered in this research is connected to the empirical study (Diener et al., 1978).

1. Harm to participants – The participants of the interviewee may get harmed at a professional and personal level. The employees are not allowed to become part of any external study as per their employment contract. Such involvement can cause harm to participants' self-development and career prospects. To avoid this, the identity of the concerned people has kept secret and instead listed it as anonymous.
2. Lack of informed consent – Information about the purpose of study, organization involved, and the technique of gathering the data are informed to the participants. The scope and aim of the study have shared with the participants in advance to think and respond.

3. Invasion of privacy – Issues regarding the privacy of participants are considered using confidentiality or non-disclosure agreement for personal and professional information (Bryan et al., 2011). In this study, verbal assurance was given to the participants about privacy and it was agreed not to share personal information in any way.

4. Deception Involvement – Deception in research is presenting something then what it is in reality. For instance, pretending to be a student while working in some organization to gather information from other companies. In this study, the students shared the details of the student’s academic background and the academic research group for authenticity.

5.2.2 Empirical Study

For the empirical study, the data was collected through various sources. For example, the annual report reports of APIs suppliers, articles, and various study reports on the Indian APIs market was used. The qualitative interviews were conducted based on set questions (Annexure 1). One audio interview was done over the internet phone call. The questions set was shared before the interview to make it more productive and fruitful. An interview was 45 minutes, and was transcribed after the interview.

To be clear and explicit about the research method and analysis to avoid the subjectivity in qualitative analysis (Greener, 2008). There are many different qualitative methods to carry out research. For this specific research, only two methods were used: qualitative collection and analysis of secondary data such as reports and other official documents and qualitative interviewing.

1. Collection and qualitative analysis of secondary data (texts and documents) – Official documents such as annual reports, government survey reports, policy documents, etc. were used. Some reports were purchased while others were available on a public platform without any constrained access.
2. Qualitative Interviewing: In this study, we utilized semi-structured interviews. The interview questions were shared with the interviewee before conducting the interview. Questions may not follow on exact flow as planned. Some questions that are not included in the reference document might be answered as the interviewer comes across something interesting an unexpected (Bryman et al., 2011). The interview was taken over the phone, recorded and then later transcribed. Ethical issues such a breach of communication agreement of the employees with their company and informed consent to the company was a hindrance in gathering data. One participant preferred to write answers to the questionnaire rather than an audio interview. The details about the PLATINEA project are shared with the participants, along with the purpose of the study.

The empirical data involved in the main study are interviews and documentations.

<table>
<thead>
<tr>
<th>Type of Study</th>
<th>Subject of the study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interviews</td>
<td>Anonymous, Supply Chain Manager</td>
</tr>
<tr>
<td>Documentation</td>
<td>Annual Reports, 2018</td>
</tr>
<tr>
<td></td>
<td>India API Market Outlook 2022</td>
</tr>
<tr>
<td></td>
<td>EXIM Report, 2018</td>
</tr>
<tr>
<td></td>
<td>Pharmaexcil, 2016</td>
</tr>
<tr>
<td></td>
<td>Dun &amp; Bradstreet India, 2016</td>
</tr>
<tr>
<td></td>
<td>Articles</td>
</tr>
</tbody>
</table>

*Table 1 - Summary of the Empirics*

5.3 **Limitations of Methodology**

Even though the research is prepared carefully, there were some limitations regarding the empirical data. Because there is a strong connection between the pharmaceutical industry and active pharmaceuticals ingredients manufactures, it was difficult to find the information sources focused on the API manufacturers without the overall context of the pharmaceutical industry. It was challenging to convince people to participate in this study as the information we asked for is sensitive to their company.
Some of the reports on the Indian API market are private and cannot be accessed without membership. The geographical boundaries also created some challenges as approaching the supply manager in person and conducting a physical interview which might give more insight. Time is a significant limitation as people take time to respond to email and convincing over the email is difficult as well. At least two-three emails are required to finally persuade the participants to take an interview and share some insight into the subject matter.

Another limitation is the difference in the scale of interviewees as the interviews are conducted from employees working at different levels, which can potentially affect the outcome. The number of interviews is also less to come up with any conclusive result and trend.
6. Empirical Data

The APIs manufacturers in India are making great efforts to increase their production capacity, modifying the processes, and making a footprint on the global market. The total production of APIs in India was valued at 11 Billion US dollars in the 2016 financial year, and it is expected to grow with 9 % CAGR between 2016-2022. The government is taking initiatives to boost the growth of the APIs market in India by developing APIs Mega Parks, increasing investment in R&D, and developing new distribution channels for global outreach. (Indian API Market Outlook, 2016). “Some of the common APIs in the Indian API market are Clopidogrel Bisulfate, Atorvastatin, Amoxycillin, Albendazole, Linagliptin.” (ASSOCHAM, 2016, P.g 2).

The Indian APIs market is divided into captive and merchant markets. The captive market includes the production of APIs by pharmaceuticals companies for their needs and business, whereas merchant includes selling of APIs by third parties. In 2016, the captive market dominated the API market by holding 65 %, and the merchant was holding 30 % of the market. (ASSOCHAM, 2016). For small markets such as Sweden, it might be an excellent opportunity to contact merchants to supply APIs in Sweden.

![Figure 3 - Indian Pharma Export in 2017-18 (Pharmaexcil, 2018)](image)

In the European market, Germany is the leading destination for bulk drug import from India (Pharmaexcil, 2018). India exports both bulk drugs and intermediates, and formulations and
biological products. The share of bulk drugs is 25% of the total export of pharmaceuticals (EXIM, 2016).

6.1 Major Players in India

Based on the revenue of the company, some of the leading API manufacturers in India are Teva, Dr. Reddy’s, Aurobindo, Cipla, Sandoz, Sun Pharma. The study also includes the national players such as Cadila, Jubliant Life Sciences, Glenmark Pharmaceuticals, Shasun Pharmaceuticals, currently exporting APIs to the global market to show the potential of APIs manufacturer as a supplier to Sweden.

The key stakeholders are the employees, shareholders, customers, government, consumers, communities, suppliers/vendors, and regulatory bodies in the pharmaceutical industry (Dr. Reddy’s, 2018).

The study includes the historical development of the pharmaceutical companies, which might hold some insight into the company strategy such as merger and acquisitions or launch in the new global market and other business units. Furthermore, analyzing the company’s current offering and future market aspiration might help to understand the trend in the pharmaceutical industry based on the released reports.

6.1.1 Dr. Reddy’s Laboratories Ltd

Dr. Reddy’s API business offers high-quality APIs across the globe including the US, Europe, Japan, China, Korea, and Latin America. There are about 250 APIs in the company’s portfolio. The most important part of the company is the existence of a responsive supply chain that can handle the dynamic market changes such as sudden surges in demand and subsequent shortages of drugs in the market. The API business is also supported by Custom Pharmaceutical Services (CPS), which helps the other companies from the development phase till formulations. To maintain the international standard, the company has implemented sustainability initiatives for eliminating waste and conserving resources. For instance, setting up ‘zero liquid discharge’ facilities to treat waste produced in manufacturing units. (Dr. Reddy’s, 2018)
The business units of Dr. Reddy’s Lab are

**Global generic** – The company offers about 200 generic drugs and this business constitute 80% of net revenues.

**Pharmaceutical Services and Active ingredients** – The company is one of the world’s largest API manufacturer. It offers end-to-end product development and manufacturing services. This business units holds 16% of net revenue. Dr. Reddy’s provides APIs in therapeutic category as Anti – Allergy, Anti- Asthma, Anti-Alzheimers, Anti-Anaemic, Anti-Angina and many more.

**Proprietary products and others** – These are to offer development of differentiated formulations. This holds about 4% of net revenue. (Dr, Reddy’s, 2018)

Dr. Reddy’s was founded in 1984 as a APIs manufacturer and in the past, it has made a many strategic moves from expanding globally by acquire overseas companies and starting new business units such as formulations. (Dr, Reddy’s, 2018)

<table>
<thead>
<tr>
<th>Years</th>
<th>Milestones</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>Acquires OctoPlus N.V., Netherlands, a service-based specialty pharmaceutical company.</td>
</tr>
<tr>
<td>2011</td>
<td>Receives ‘Outstanding Export Performance for 2010–11’ in the ‘Large Scale Industry’ category</td>
</tr>
<tr>
<td>2009</td>
<td>Strategic Alliance with GlaxoSmithKline.</td>
</tr>
<tr>
<td>2007</td>
<td>Launches the world’s first biosimilar of a monoclonal antibody.</td>
</tr>
<tr>
<td>2005</td>
<td>Acquires Roche’s API business in Mexico.</td>
</tr>
<tr>
<td>2000</td>
<td>Become India’s third largest pharmaceuticals company.</td>
</tr>
<tr>
<td>1995</td>
<td>Global expansion in highly regulated market such as USA.</td>
</tr>
<tr>
<td>1991</td>
<td>Launched Omez (Omeprazole).</td>
</tr>
<tr>
<td>1987</td>
<td>Started its formulations operations.</td>
</tr>
<tr>
<td>1984</td>
<td>Began as an API manufacturer for the Indian market.</td>
</tr>
</tbody>
</table>

*Table 2 - Historical Development of Dr. Reddy’s Lab*

The company has eight production unit which are inspected by USFDA (United States Food and Drug Authority). Six of them are in India and other two are in Mexico and the UK. The production units are also complemented by formulation facilities (Dr, Reddy’s, 2018).
6.1.2 Cadila Pharmaceuticals

Cadila is one of the top active pharmaceutical ingredient manufacturers of the world. The company has massive manufacturing facilities in India, Japan, Europe, and Australia. The company is driven by research and innovation and believes in developing affordable medicine for patients (Cadila, 2018).

Business units:

**Active pharmaceutical ingredients (APIs)** – They offer 38 APIs and intermediates in a therapeutic category such as respiratory, diabetology, gastroenterology, antimigraine, orthopedics, and many more. With 31 drug master files and 12 certificates of Suitability and many more in the pipeline, Cadila pharmaceutical's strategic focus is on increasing the API portfolio.

**Formulations** – Cadila pharmaceutical offers more than 850 finished dosage products belonging to 45 therapeutic areas and 12 specialties. There are three manufacturing facilities for formulation in Gujarat, Jammu & Kashmir (India) and Ethiopia.

**Contract research operation (CRO)** - At Cadila CRO series of pre-clinical and clinical trials are offered to accelerate the client's drug development processes using in house talent and world-class resources. Cadila helps in developing formulation, herbal products, API solutions, pre-clinical and clinical research, and biotechnology. (Cadila, 2018)

<table>
<thead>
<tr>
<th><strong>Years</strong></th>
<th><strong>Milestones</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>2004</td>
<td>Innovated drugs in cardiovascular, lung and tuberculosis.</td>
</tr>
<tr>
<td>2004</td>
<td>Established first plant in Ethiopia with WHO.</td>
</tr>
<tr>
<td>1996 - 2006</td>
<td>Expanded to manufacturing of bulk drug and APIs, formulations.</td>
</tr>
<tr>
<td>1995</td>
<td>Restructured as Cadila Pharmaceuticals.</td>
</tr>
<tr>
<td>1970</td>
<td>Awarded ad Medicine Man of India for developing necessary drug for marginalized.</td>
</tr>
<tr>
<td>1952</td>
<td>Founded Cadila Laboratories with vitamin syrup as first product.</td>
</tr>
</tbody>
</table>

Table 3 - Historical Development of Cadila Pharmaceuticals

The company exports APIs to the United States, Brazil, and Mexico in Latin America, France, and Spain. The company has 32 manufacturing facilities in India, the US, and Brazil. Out of 32, 28 facilities are for the manufacturing of API and formulations. There are around 20 locations in
India where manufacturing and formulation take place. The company has launched the APEX (API Performance Excellence) program to deliver the end to end operations of API to increase optimization in the business model. (Cadila, 2018)

6.1.3 Aurobindo Pharmaceuticals

Aurobindo is one of the leading Indian APIs suppliers serving various generic and branded drugs with strong regulatory capability with 227 US DMF filings as of March 31, 2018 (Annual report, 2018). The company’s internal operations are cost-effective with vertical integration of around 70% of API requirements sourced internally. The company is a market leader in Semi-Synthetic Penicillins and has a presence in key therapeutic segments such as neurosciences, cardiovascular, anti retrovirals, anti-diabetics, gastroenterology, and anti-biotics. (Aurobindo, 2018)

**Business units:**

**Formulations** – The company provides manufacturing of generics/ Branded generics, product out-licensing, and contract manufacturing.

**Custom Synthesis** – The company provides project-based chemistry services to outsourcing companies.

**Research and Development** – The company is working on developing new innovative drugs and creating a chemical synthesis, high-quality formulation, and developing a drug developing system.

**API** – The company focuses on both manufacturing and developing APIs. It is one of the few companies which provide penicillin and cephalosporins along with penams. (Aurobindo, 2018)

<table>
<thead>
<tr>
<th>Years</th>
<th>Milestones</th>
</tr>
</thead>
<tbody>
<tr>
<td>2017-18</td>
<td>Signed agreement with Sandoz, Acquired Generis in Portugal</td>
</tr>
<tr>
<td>2014-16</td>
<td>Acquired commercial operations of Actavis Plc. (Western Europe)</td>
</tr>
<tr>
<td>2010-11</td>
<td>Partnership with AstraZeneca</td>
</tr>
<tr>
<td>2007-08</td>
<td>Acquired marketing authorization with TAD Italy</td>
</tr>
<tr>
<td>2005-06</td>
<td>Acquired UK based Milpharm Ltd.</td>
</tr>
<tr>
<td>2004-05</td>
<td>Acquired sterile plant of Dee Pharma</td>
</tr>
</tbody>
</table>
Aurobindo's strategic focus is on strengthening and diversifying the existing portfolio with the creation of robust R&D and manufacturing capability and capacity in India. Also, the creation of a fully automated distribution center and an integrated supply chain and marketing structure. (Aurobindo, 2018)

The company focused on mergers and acquisitions in the past and invested in a joint venture with some other global pharmaceutical companies. The company also provides APIs such as penicillin and cephalosporin, which are unavailable in Sweden.

### 6.1.4 Sun Pharmaceutical Industries

Sun Pharma is the world’s fifth largest specialty generics pharmaceutical company. There are 40 manufacturing facilities across 6 continents. The business is a mix of 68% international and 32% India. (Sun Pharma, 2018).

**Business units**

**Formulation-** The company is targeting specialty and generic products in chronic and acute treatments. Sun pharma is the number one pharmaceutical company in Indian branded generics ranked number one by 13 classes of doctor categories. Sun Pharma has a leading position in high-growth chronic therapies and specializes in technically complex products. (Sun Pharma, 2018).

**Active Pharmaceutical Ingredients (APIs) business-** Sun Pharma manufactures over 400 APIs across 14 locations while adding approximately 20 APIs to its portfolio annually. The company’s strategic focus is on expanding existing APIs portfolio to extend the scope of its API operations to ensure long-term supply relations with global customers. The therapeutic segments are
Cardiology, Diabetes, and Metabolic disorders, Gastroenterology, Ophthalmology, Oncology, Dermatology, Pain, Allergy, Asthma and Inflammation, Gynecology. (Sun Pharma, 2018).

<table>
<thead>
<tr>
<th>Years</th>
<th>Milestones</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014- 16</td>
<td>Acquired some more pharma company in US, Australia and Russia.</td>
</tr>
<tr>
<td>2013</td>
<td>Acquired Ranbaxy</td>
</tr>
<tr>
<td>2008 - 12</td>
<td>Acquired Chattem Chemicals Inc., US and others two US company and one in Isarel.</td>
</tr>
<tr>
<td>2005</td>
<td>Acquired ICN’S business from Valeant Pharma, Hungary</td>
</tr>
<tr>
<td>2004</td>
<td>Acquired Phlox Pharma</td>
</tr>
<tr>
<td>2000</td>
<td>Acquired Pradeep Drug Company</td>
</tr>
<tr>
<td>1997</td>
<td>First international acquisition of Carco Pharma Ltd. USA.</td>
</tr>
<tr>
<td>1996</td>
<td>Expanded sales network to 26 countries</td>
</tr>
<tr>
<td>1991</td>
<td>Established R&amp; D unit</td>
</tr>
<tr>
<td>1989</td>
<td>Launched gastroenterology products in India</td>
</tr>
<tr>
<td>1983</td>
<td>Founded with formulation manufacturing plant for five psychiatry drugs.</td>
</tr>
</tbody>
</table>

Table 5 - Historical Development of Sun Pharma

Sun pharmaceutical established in 1983 after series of acquisitions and alliances has grown into a global company serving more than 100 markets with 24 plus manufacturing sites producing more than 2000 marketed products (Sun Pharma, 2018).

6.1.5 Glenmark Pharmaceuticals Ltd.

Glenmark is an Indian based pharmaceutical company headquartered in Mumbai India. Glenmark is ranked 75th among the global pharma companies and has 16 manufacturing facilities for formulations and APIs in four continents. Glenmark has offices in 50 countries and employs 13,500 employees, generating 70% of its annual revenues from international markets. (Glenmark, 2018)

Business Units

Active pharmaceutical ingredients business - Glenmark operates active pharmaceutical ingredients business under Glenmark life sciences which have a total of 262 inventions in API
with at least 49 patented APIs. With an annual addition of six to eight products to its portfolio. (Glenmark, 2018)

<table>
<thead>
<tr>
<th>Years</th>
<th>Milestones</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015 - 17</td>
<td>Making respiratory a focus area with the focus on continuous innovation</td>
</tr>
<tr>
<td>2014</td>
<td>Expanded manufacturing operations US and Switzerland</td>
</tr>
<tr>
<td>2007</td>
<td>Expanded operations to US market</td>
</tr>
<tr>
<td>2005</td>
<td>Out-licensing deal for novel molecules</td>
</tr>
<tr>
<td>2001</td>
<td>Diversified to API manufacturing</td>
</tr>
<tr>
<td>1999</td>
<td>Glenmark commissioned the sinnar R&amp;D center in Maharashtra</td>
</tr>
<tr>
<td>1977</td>
<td>The year Glenmark was established</td>
</tr>
</tbody>
</table>

Table 6 - Historical Development of Glenmark.

6.1.6 IPCA Laboratories

Ipca has been partnering with other global pharmaceutical companies to supply formulation and APIs. The company works with AstraZeneca, GlaxoSmithKline, Merck, Roche, and Sanofi Aventis over the years (Ipca, 2018).

Business units

APIs Manufacturing - Ipca is a market leader in the Indian APIs market, both in the anti-malarial and anti-hypertensive therapeutic segments. The company exports its APIs across the globe. Most of the international customers of the company are end-user formulations manufacturers, including several multinational companies. (Ipca, 2018)

The formulation for Branded and Generic market - Ipca has over 1500 products registered in 70 countries, and another 600 are in the process of registration in 50 countries. More than half of the formulations business is backed by the company own APIs. (Ipca, 2018)
<table>
<thead>
<tr>
<th>Years</th>
<th>Milestones</th>
</tr>
</thead>
</table>
| 2018  | Acquired of Pisgah Labs Inc., USA (Pisgah)  
        | Acquired of 80% share capital of Bayshore Pharmaceuticals LLC, USA. |
| 2006  | Strategic alliance with Ranbaxy Pharmaceuticals Inc. for the U.S market. |
| 2003  | Launched new domestic marketing division for Cardio-Diabetology.  
        | Incorporated in USA. |
| 2002  | Incorporated 'Laboratories Ipca Do Brasil Ltd.' in Brazil. |
| 2001  | Acquired 'National Druggists (Pty) Ltd.’ in South Africa.  
        | Incorporated 'Ipca Pharma Nigeria Ltd.' in Nigeria. |
| 1994  | Acquired API manufacturing plant from BDH Pharmaceuticals (a subsidiary of E-Merck) in India. |
| 1993  | Acquired Hoechst India's formulations unit at Kandla. |
| 1984  | Started API manufacturing business. |
| 1978  | Started formulations business. |
| 1976  | Started with marketing drugs in India |

Table 7- Historical Development of Ipca Laboratories.

It is been analyzed that Ipca is very aggressive in expanding the API and formulation business all over the world. So far, the company is using the strategy of merger and acquisition of other pharmaceutical companies and side by side working on increasing the quality standard of their manufacturing units by getting certified by WHO (World Health Organization), USDFA to unleash the regulated markets. The company also follows the strategy of partnering with other pharmaceutical companies to supply the APIs.

### 6.1.7 Virchow Laboratories

Established in 1983, Virchow group comprise of six independent, active pharmaceutical ingredients (API) companies. According to the official website of Virchow laboratories, the following are the business units of the company along with the historical developments over the last two decades (Virchow, 2018).

Business units are Active pharmaceutical ingredients, Pipeline APIs, Intermediates, Bulk chemicals.
### Historical Development of Virchow Laboratories

<table>
<thead>
<tr>
<th>Years</th>
<th>Milestones</th>
</tr>
</thead>
<tbody>
<tr>
<td>2017</td>
<td>Group revenues cross 3000 cores ($500 million)</td>
</tr>
<tr>
<td>2014</td>
<td>Group revenues cross Rs 2000 crores.</td>
</tr>
<tr>
<td>2012</td>
<td>Started manufacturing of Sterile Cephalosporins at Covalent.</td>
</tr>
<tr>
<td>2009</td>
<td>Started marketing of formulations in international markets.</td>
</tr>
<tr>
<td>2007</td>
<td>Started manufacturing of GCLE, a key Cephalosporin intermediate at Virchow petrochemicals.</td>
</tr>
<tr>
<td>2004</td>
<td>Acquisition of Andhra Organics in Vizag.</td>
</tr>
<tr>
<td>2003</td>
<td>First US FDA approval in Group for Virchow Labs.</td>
</tr>
<tr>
<td>2002</td>
<td>Saraca labs become part of Virchow Group through majority share acquisition by promoters of Virchow Group.</td>
</tr>
<tr>
<td>2001</td>
<td>Virchow Biotech incorporated for manufacture of recombinant and classical biologicals in collaboration with US based scientist group</td>
</tr>
</tbody>
</table>

Table 8 - Historical Development of Virchow Laboratories

### 6.2 Scarce Antibiotics and their respective APIs suppliers in India

The shortage of antibiotics is an emerging threat to many countries. The excessive use of antibiotics developed antibiotics resistance and need of new drugs to fight against the microbes causes disease to human body. In Sweden, the shortage of the antibiotics mentioned below are reported since 2018.

<table>
<thead>
<tr>
<th>Product (ATC)</th>
<th>Date of information about insufficient availability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ceftibuten</td>
<td>Deregistered May 2017</td>
</tr>
<tr>
<td>Eusaprim forte</td>
<td>March 2018</td>
</tr>
<tr>
<td>Piperacillin/Tazobactam</td>
<td>April 2017</td>
</tr>
<tr>
<td>Furadantin</td>
<td>Dec 2017</td>
</tr>
<tr>
<td>Cefadroxil</td>
<td>Sep 2017</td>
</tr>
<tr>
<td>Spektramox</td>
<td>Jan 2018</td>
</tr>
<tr>
<td>Spektramox</td>
<td>March 2018</td>
</tr>
</tbody>
</table>

Table 9- Reported Insufficient availability of antibiotics (Svarm, 2017)
After analyzing the database from EudraGMDP and FDA of the United States, the exporter of shortage APIs from India are studied. The table below includes the antibiotics along with their respective active pharmaceutical ingredients which were recorded to be short by the health agency of Sweden.

<table>
<thead>
<tr>
<th>Product</th>
<th>Substance (API)</th>
<th>API Exporting Company (India)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ceftibuten</td>
<td>Cephalosporin Antibiotic</td>
<td>Taj Pharmaceutical Limited., Aurobindo Pharmaceuticals</td>
</tr>
<tr>
<td>Eusaprim forte</td>
<td>Sulfamethoxazole &amp; trimethoprim</td>
<td>Virchow Laboratoties Limited. Cadila Pharmaceuticals</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Indosol Drugs Ltd.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Inventaa Chemicals Ltd.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IPCA Laboratories Ltd.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Andhra Organic Ltd.</td>
</tr>
<tr>
<td>Piperacillin &amp; Tazobactam</td>
<td>Piperacillin</td>
<td>Cadila Pharmaceuticals</td>
</tr>
<tr>
<td></td>
<td>Tazobactam sodium</td>
<td>Bioburg lifescinces</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sterile India Pvt Ltd.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pfizer Healthcare India</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Aurobindo Pharma Ltd.</td>
</tr>
<tr>
<td>Furadantin</td>
<td>Nitrofurantoin</td>
<td>Cadila Pharmaceuticals</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CI Chemicals (India) Pvt. Ltd.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Mylan Laboratories Ltd.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Srini Pharmaceuticals Ltd.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Unimark Remedies Ltd.</td>
</tr>
<tr>
<td>Cefadroxil (Cephalosporin-type antibiotic)</td>
<td>Cefadroxil monohydrate</td>
<td>Aurobindo Pharma Ltd.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sun Pharmaceuticals Industries Ltd.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Orchid Pharma Ltd.</td>
</tr>
<tr>
<td>Spektramox</td>
<td>Amoxicillin trihydrate</td>
<td>Cadila Pharmaceuticals</td>
</tr>
<tr>
<td></td>
<td>Potassium clavunate</td>
<td>Sun Pharmaceuticals Industries Ltd.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Aurobindo Pharma Ltd.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Surya Pharmaceuticals Ltd.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Titan Pharma Pvt Ltd.</td>
</tr>
</tbody>
</table>

*Table 10 - APIs suppliers in India*
6.3 Challenges for Exporting

There are many drivers and challenges for APIs manufacturers to increase production and to invest more in setting up a new manufacturing facility. The domestic drivers are

- Increase in healthcare expenditure
- Growing burden of the aging population
- Patent expiry of some of the blockbuster drugs in the coming years.

The patent cliff will provide the opportunity for APIs manufacturers to develop generic APIs for domestic as well as global markets. (ASSOCHAM, 2016)

The challenges for API manufacturers in India are a dependency on low-cost raw material from China and need help to build up capacity and freedom in the environmental regulatory forum. (ASSOCHAM, 2016)

The demotivating factors in investing in new manufacturing units for APIs manufacturer are

- Complex license renewal process shifts to developing formulation business.
- Lack of infrastructure for APIs manufacturers such as tech park, trade zones, export processing zones.
- Lack of government support in terms of subsidized facilities.
- The stringent government policies such as good manufacturing practices implementation and auditing
- Price control policy which makes the manufacturer keep the price low so that common people can get cheap medicine. (ASSOCHAM, 2016)

It might influence the APIs manufacturers to supply APIs in the global market to increase their profits.

The European pharmaceutical companies are opting for offshore outsourcing of raw material from low labor cost countries such as India, China. (Huq et al., 2016). The outsourcing from India might be a good option, but the high level of interaction and coordination process increased the complexity of the supply chain. It might lead to an operational, quality standard, cultural, and business practice issues with the companies from the supplier side.
7. Empirical Analysis

Many supply chain managers from the Indian Pharmaceutical industry were contacted. Most of them didn’t agree to comment anything on company’s strategy and their internal process of managing the demand and stocks. The participants agree to keep the identity anonymous due to company policy. The interviewee are from different pharmaceutical companies.

<table>
<thead>
<tr>
<th>Interviewee</th>
<th>Location</th>
<th>Type of Interview</th>
<th>Call Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supply Chain Manager 1 (SM1)</td>
<td>India</td>
<td>Phone call</td>
<td>45 mins</td>
</tr>
<tr>
<td>Supply Chain Manager 2 (SM2)</td>
<td>India</td>
<td>Written Answers</td>
<td>Not Available</td>
</tr>
</tbody>
</table>

*Table 11 - Interview Details*

7.1 Interview Insights

To understand how pharmaceutical companies are managing the demand and stocks to keep the seamless supply of APIs to their clients in India and abroad, the following questions were framed.

The SM1 commented on the supply chain of API manufacturing companies. For API manufacturing companies, the formulation companies are the clients. The suppliers for API manufacturers are raw material providers.

When asked if the company is exporting APIs to Sweden or any other European countries, the SM1 replied that the company is exporting to European countries but not particularly to Sweden. The last export of APIs to Sweden happened in 2016, and the SM2 replied that the company is exporting to European countries but did not specifically mention the export of APIs to Sweden.

When asked about the external stakeholders that support exports of APIs to the foreign market, the SM1 replied that end customers and nominated agency, the end customer nominated for the API supplies, play an essential part in global sales. The formulation companies have their appointed agency (middle man) who deals with API manufacturers. Similarly, the SM2 replied
that there are regulatory authorities such as CDSCO, EDQM, WHO, logistical service providers, packaging partners, distributors (in some cases) that act as the external stakeholders in the business.

When asked about the internal factors that support/challenge the export of APIs to the foreign market. The SM1 replied that supply chain, production, quality assurance, quality control, and marketing are internal factors that affect the export of APIs in the foreign market. The internal supply chain starts with the procurement of raw materials to product delivery. The raw material is sent to quality analysis before production. Sometimes API manufacturer procures the intermediate to decrease the cycle time of production. After the production, the API manufacturer shares a certificate of analysis with clients and delivers the products to the middle man. The SM2 chooses not to comment on this question.

About the communication channels (Middle man/Broker) used in the pharmaceutical industry, The SM1 replied that firstly the formulation companies have the nominated agency that deals with the supply of APIs. Secondly, there are traders in India who act as middlemen and contact API manufacturers to fulfill the demand. Also, there is no online platform for traders or suppliers as companies do not want to reveal their competitive strategy. However, the SM2 replied that the company has its own marketing office in European countries to get the demand and sell the products.

When asked about the minimum duration of the contract requires for exporting APIs, SM1 and SM2 both mentioned that the annual contract is very common in the pharmaceutical industry. The pricing sometimes changes which has to get agreed by both parties; otherwise, the agreement gets terminated.

When discussed the degree of responsibility (environmental etc.) that lies on the APIs suppliers under the contractual agreement in terms of meeting the specified delivery schedule, the SM1 replied that the contract is allocated to the company based on their credentials. The company has to deliver the product on time. Transporting the APIs to customers in a controlled environment comes under the responsibility of APIs manufacturer. The SM2 replied that Liquid discharges that are the byproduct of API production (solvent etc.) are to be disposed
of properly. PCB limits are stringent on API manufacturers. Most of the partners have “fail to supply” clauses.

For demand and production planning, the SM1 replied that the company has long lead time to prepare the order, which is about 45 to 90 days. Usually, the company has four months of demand beforehand. The SM2 replied that developing capacity to match demand fluctuations is difficult in API. Thus most of the time, companies have additional capacity in place as a cushion. Raw material supply fluctuations impact API supply significantly.

The management of APIs stocks and the raw material is done based on lead time. The SM1 replied that the lead time for delivering the product varies from 45 to 90 days. The raw material lead time is 15 days for domestic suppliers and 45 days from international suppliers. The three months of the stock is the norm in a company as per the SM2. The company also keeps long term contracts with suppliers to manage the stocks.

The SM1 commented that the Indian market is not very regulated in comparison to the US and European markets. It is difficult to comment on the Indian Drug Regulatory authority. The SM2 highlighted that the delay in export permissions does impact supply and export to the global market.

When asked about drug price control as a hindrance in the growth of APIs manufacturers and its effect on contracts with foreign partners, specifically Sweden, the SM1 replied that India does regulate the price of drugs but also provides subsidies for those drugs. The pricing for all the drugs is not controlled by the Indian government, but it might get affected by other factors such as USFDA. However, the drug price controls in India are relevant to the India market. Indian regulators don’t have price controls for exports.

7.2 Porter FFM Analysis

Porter’s five forces are analyzed based on the empirical study of the pharmaceutical industry to understand the competitive advantage of the pharmaceutical companies, especially focused on APIs business.
**Rivalry among existing competitors:** The pharmaceutical market is highly competitive due to the presence of large and small companies. All the API manufacturers in India are in the race to strengthen their production, sales, and marketing capabilities to produce higher quantities and increase their exports to foreign countries. The competition among the players providing generic active pharmaceutical ingredients (APIs) is comparatively high as compared with the competition for non-generic APIs. The market for new drugs gives the patent-holding company an edge over the pricing and market share, but for generic drugs, the entry barrier is not so high, which makes it more competitive. Many established API producers in which high R&D investments and proper regulatory certifications have a competitive edge over small players.

**The threat of new entrants:** From the pharmaceutical industry viewpoint, the new entrants will be constrained by huge capital investment in research and development or setting up laboratory or manufacturing units. Also, the stringent government regulation and approval act as an entry barrier for the new players. But the shift in business approaches such as contract research and manufacturing and market holding authorization can bypass the clinical trial and drug discovery and directly sell the drugs in the market. Thus, the new entrants are low competitive forces due to entry barrier and regulatory constraints. However, in the active pharmaceutical ingredients (APIs) market, it has been observed that the threat of new entrants is high both from domestic players in the Indian market and the international players such as the growing market for the Chinese APIs.

**Bargaining power of suppliers:** There are many companies in the market offering the same drugs. In such a scenario, buyers such as hospitals, municipal committees, and health organizations have more bargaining power than suppliers. In the case of active pharmaceutical ingredients (APIs) market, the suppliers experience low bargaining power regarding generic APIs due to the presence of a large number of players in the market and strict regulatory requirements. However, when it comes to the non-generic APIs, the number of actors decreases, allowing suppliers to experience a moderate degree of bargaining power.
Bargaining power of buyers: There are many drug manufacturers in the market, and for that reason, the pharmaceutical companies have an edge to bargain over the pricing. The pharmaceutical companies can easily switch from one supplier to another suppliers. Strict and redundant regulatory scenarios along with the option of cheap sourcing APIs from China favor the buyers to hold a certain degree of bargaining power when it comes to sourcing APIs from Indian API producers.

The threat of substitute products or services: In the pharmaceutical industry, there is a high threat of substitutes for a drug or a generic version of drugs. The manufacturer does not incur the cost of research and development, FDA approval, and clinical trials. Low-quality APIs from China which is favored by the Indian pharmaceutical producers to save costs is a big threat to the growth of the local APIs industry. The risk will grow even higher with the improvement of quality.
standards by the Chinese API producers and the R&D of the new API types. Therefore, the manufacturer can offer lower prices and contribute to a threat to an existing manufacturer.
8. Discussion

The pharmaceutical industry is highly competitive and dynamic, with many big and small players. The different classes of companies depending on their business goals, have different business strategies to maximize profits and market reach. Based on secondary data, Cadila Pharma, Aurobindo, and Sun Pharma are the leading Indian manufacturers and exporter of APIs that are scare in Sweden. The past strategic business moves of these companies explained that they have been adopting the merger and acquisition strategy to expand in international markets. Also, some of them have made the joint investment to penetrate other countries for APIs business. The big APIs producers sell their APIs through their marketing office in other continents or through joint alliances with other pharmaceutical companies in those continents. However, small companies rely on traders or distributors known as the middle men to export APIs into the global market.

The big pharmaceutical companies are shifting their focus from the manufacturing of raw materials to procuring raw materials. The outsourcing has allowed these companies to save costs and increase their investigation and development (R&D) investments. When it comes to the sourcing of raw materials, the pharmaceutical companies employ different sourcing strategies discussed extensively in the theory section under sourcing of APIs. These different sourcing strategies have resulted in the creation of complex supply chain networks with dependency on several actors for the procurement of active pharmaceutical ingredients.

Several factors have made it hard for the pharmaceutical companies in the developed regions to produce APIs at their place of operations, as discussed in the theory section. Thus, the manufacturing of pharmaceutical products by pharmaceutical companies is greatly dependent on the efficient procurement of active pharmaceutical ingredients (APIs) from other regions.

In this research, the major Indian APIs producers for the reported scarce antibiotics were identified. These major players were classified based on their portfolios and maximum possible relevance to the APIs used in the production of antibiotics which suffer shortages in the Swedish market. These Indian APIs manufacturers are exporting the shortage of APIs to other countries. It can be concluded that the quality and good manufacturing practices of APIs manufacturers would be acceptable to pharmaceutical companies in Sweden.
The APIs supplier has an annual rate contract with the client to supply the APIs. The price can be renegotiated after one year if the client agrees with the increase in price. The big companies such as Aurobindo, Cadila, Sun Pharmaceuticals have a greater share in the total exports of APIs from India. Apart from that, small companies such as IPCA, Glenmark, Virchow Laboratories, Inventaa, Taj pharma, Titan Pharma, etc. are some of the companies which have a proportionate share in exports of APIs to the European market.

8.1 Policy Implications

Indian pharmaceutical market is mostly unregulated with a large number of API producers, and it is important to import APIs from GMP (Good Manufacturing Practices) certified API suppliers or other certification as per the region such as the USFDA. There is a presence of a large number of unregistered API producers in India, companies mentioned in this thesis have a proven track record of operating at both national and international levels and are certified by both the local and the global regulatory agencies.

8.2 Implications for Business

The Indian government is also an important entity in uplifting the APIs market and is continuously working on providing excellent infrastructure and regulatory systems to support growth both in domestic and international markets. Although the low-cost APIs sourced from China have a growing influence in global markets, there are challenges to choose the one with quality and good manufacturing practices due to presence of so many small APIs manufacturing. This gives the Indian manufacturers a competitive edge.
9. Conclusion

Dr. Reddy Labs, Cadila Pharma, Aurobindo, and Sun Pharma are some of the leading APIs manufacturers in India. Currently, they are exporting APIs to highly regulated markets such as the USA and Europe. It can be inferred that they are implementing good manufacturing practices and also certified by USFAD.

Most of the companies offer both APIs manufacturing and formulations on an annual rate contract basis and follow the business strategies such as merger and acquisitions and joint ventures for global expansion. The communication channels for business are marketing offices for big companies and nominated trade agencies for medium and small enterprises.

The threat of new entrants, rivalry among existing competitors, and the threat of substitutes are very low for APIs manufacturers. The threat of new entrant and substitute forces require a lot of time and capital investment. The bargaining power of APIs buyers is more than APIs suppliers. But for scarce APIs, the suppliers have more control over bargaining than buyers because of not so many options for buyers.

Through this study, it can be concluded that there is a strong potential for exports or outsourcing of APIs from India to establish and maintain a stable supply of APIs. This study could help those who want to understand the export strategies of big, small, and medium-sized Indian APIs manufacturers. It can help to understand the competitive forces that have more power in the Indian APIs market.
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ANNEXURE 1

Q1. Is the APIs supplier exporting to Sweden or any other European countries?
Q2. Who are the external stakeholders to support exports of APIs to the foreign market? E.g. regulation and export taxes.
Q3. Who are the internal factors to support/ challenge export of APIs to the foreign market? E.g. production process, R&D facilities.
Q4. What kind of communication channels (Middle man / Broker) do APIs suppliers have to deal with the Pharmaceuticals manufacturers in Sweden?
Q5. What minimum duration of the contract do APIs suppliers usually require starting exports of APIs to the entity in the foreign market?
Q6. What is the degree of responsibility (environmental etc.) that lies on the API suppliers under the contractual agreement in terms of meeting the specified delivery schedule?
Q7. How does the production of the APIs align with the demand in the CMO market?
Q8. How does the APIs supplier manage the PAPIs stocks and raw material for APIs production?
Q9. How operational competency of Indian drug regulatory authority effects the exports of APIs to Sweden?
Q10. How policies related to pollution and treatment effects the production of APIs in response to demand? Does the sustainability is the issue for supplying to global market?
Q11. Drug price control is a hinderance in the growth of APIs manufacturers. How does this effect contracts with the foreign partners specifically Sweden?
Q12. How do you perceive the Swedish market in general?
## ANNEXURE 2

<table>
<thead>
<tr>
<th>Antibiotics</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ceftibuten</td>
<td>Ceftibuten is a third-generation cephalosporin antibiotic. Ceftibuten is a cephalosporin antibiotic used to treat certain infections caused by bacteria such as bronchitis and ear and throat infections. Antibiotics will not work for colds, flu, or other viral infections.</td>
</tr>
<tr>
<td>Eusaprim forte</td>
<td>Eusaprim forte is a combination of two antibiotics: sulfamethoxazole &amp; trimethoprim. It is used to treat a wide variety of bacterial infections (such as middle ear, urine, respiratory, and intestinal infections). It is also used to prevent and treat a certain type of pneumonia.</td>
</tr>
<tr>
<td>Piperacillin tazobactam</td>
<td>Piperacillin and tazobactam injection is used to treat pneumonia and skin, gynecological, and abdominal infections caused by bacteria. Piperacillin is in a class of medications called penicillin antibiotics. It works by killing bacteria that cause infection.</td>
</tr>
<tr>
<td>Furadantin</td>
<td>Nitrofurantoin is used to treat urinary tract infections. This medicine is an antibiotic. It works by killing bacteria or preventing their growth. However, this medicine will not work for colds, flu, or other virus infections.</td>
</tr>
<tr>
<td>Cefadroxil</td>
<td>Cefadroxil is a cephalosporin-type antibiotic used to treat a wide variety of bacterial infections (e.g., strep throat, skin and urinary tract infections). It works by stopping the growth of bacteria. This antibiotic treats only bacterial infections. It will not work for viral infections.</td>
</tr>
<tr>
<td>Spektramox</td>
<td>Amoxicillin is a penicillin antibiotic that fights bacteria. Amoxicillin is used to treat many different types of infection caused by bacteria, such as tonsillitis, bronchitis, pneumonia, gonorrhea, and infections of the ear, nose, throat, skin, or urinary tract.</td>
</tr>
</tbody>
</table>