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EVALUATING THE POTENTIAL OF RESHORING APIs TO STRENGTHEN PHARMACEUTICAL SUPPLY CHAIN RESILIENCE: AN EXPLORATORY STUDY

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MADRID | MAY 2023

Abstract

This paper is an exploratory study focusing on the evaluation of the potential of reshoring active pharmaceutical ingredients to strengthen supply chain resilience. Through an extensive literature review and semi-structured interviews of industry professionals, this paper provides a comprehensive overview of the different stages in the supply chain of medicine, identifies the disruptions and challenges in pharmaceutical supply chain management, the factors that influence the location of the production of an API, and analyses the impact that globalisation and Covid-19 had on the supply chain. Furthermore, this paper identifies ways in which companies can secure their supply chain of active pharmaceutical ingredients and identifies the distinct drivers and barriers to reshoring, along with corresponding mitigation approaches. The paper finds that partial reshoring of active pharmaceutical ingredients for core patented products is a potentially viable solution and provides recommendations such as automation, nearshoring to Eastern European countries, and public policy to mitigate the barriers to the practice. It highlights that reshoring is not essential to supply chain resilience and that there is no singular solution that can adequately address the complexity of the pharmaceutical supply chain.

Keywords: Supply Chain Management, Active Pharmaceutical Ingredients, Pharmaceuticals, API, Reshoring

Resumen

Este artículo es un estudio exploratorio centrado en la evaluación del potencial de "reshoring" de principios activos farmacéuticos para reforzar la resiliencia de la cadena de suministro. A través de una amplia revisión bibliográfica y de entrevistas semiestructuradas a profesionales del sector, este documento ofrece una visión global de las diferentes etapas de la cadena de suministro de medicamentos, identifica las perturbaciones y los retos de la gestión de la cadena de suministro farmacéutica, los factores que influyen en la localización de la producción de un principio activo farmacéutico y analiza el impacto que la globalización y Covid-19 han tenido en la cadena de suministro. Además, este documento identifica las formas en que las empresas pueden asegurar su cadena de suministro de principios activos farmacéuticos e identifica los distintos impulsores y barreras al "reshoring", junto con los correspondientes enfoques de mitigación. El documento concluye que el "reshoring" parcial de principios activos farmacéuticos para productos básicos patentados es una solución potencialmente viable y ofrece recomendaciones como la automatización, el "nearshoring" a países de Europa del Este y políticas públicas para mitigar las barreras a esta práctica. Destaca que el "reshoring" no es esencial para la resiliencia de la cadena de suministro y que no existe una solución única que pueda abordar adecuadamente la complejidad de la cadena de suministro farmacéutica.

Palabras Clave: Gestión de la Cadena de Suministro, Principios Activos, Industria Farmacéutica, API, Reshoring

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List of Abbreviations

AI	Artificial Intelligence
API	Active Pharmaceutical Ingredient
ASMF	Active Substance Master File
CAGR	Compound Annual Growth Rate
CEP	Certificate of Suitability
CEO	Chief Executive Officer
CMO	Contract Manufacturing Organisation
CPHI	Convention on Pharmaceutical Ingredients
CPO	Contract Packaging Organisation
CSCMP	The Council of Supply Chain Professionals
DMF	Drug Master File
EDQM	European Directorate for the Quality of Medicines and HealthCare
EU	European Union
FDA	Food and Drug Administration
FDF	Finished Dosage Forms
GMP	Good Manufacturing Practices
IOT	Internet of Things
IT	Information Technology
KSM	Key Starting Materials
R&D	Research and Development
SCIS	Supply Chain and Information Systems
UK	United Kingdom
US	United States
USP	The United States Pharmacopeia

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1. Introduction

This paper is an exploratory study that evaluates the potential of reshoring active pharmaceutical ingredients (APIs) to strengthen pharmaceutical supply chain resilience. Pharmaceutical supply chains should provide the correct quantity of medicines, with an acceptable quality, to the correct place and correct customers, at the right time and with optimum cost to be consistent with health system's objectives which also benefits stockholders (Kaufmann et al., 2005). Any flaw in the supply chain in this industry can have serious effects and threaten patient's life through hindering access to medicines (Schneider et al., 2010). In this way, it is critical to ensure resilient pharmaceutical supply chains.

The complexity of pharmaceutical supply chains is intensifying in today's globalised world. Since the 1990's, the production of APIs has been moving from western countries to developing countries such as India and China (Bumpas & Betsch, 2009). This has been largely driven by low production costs, fewer environmental regulations, large-scale manufacturing, and low barriers to market entry to these countries (Bumpas & Betsch, 2009). In 2020, only 33% of the Certificates of Suitability (CEPs) required in Europe were held by European manufacturers with no CEPs available in Europe for 93 APIs required in this region (Pro Generika, 2020). This has provoked vulnerabilities in the pharmaceutical supply chain due an over reliance of APIs in India and China.

The Covid-19 pandemic highlighted the gaps in pharmaceutical supply chains through exposing the dependency that the industry has on the production of APIs in China and India. World leaders and pharmaceutical companies globally have begun to pay more attention to this dependency and have been motivated to undertake restructuring efforts to address them (Mullin, 2020). Many academics believe that Covid-19 will undermine the "Global Value Chain" – a key trademark of globalisation, and make value chains more regional or domestic (Baldwin & Evenett, 2020; Baraldi et al., 2022; Enderwick and Buckey, 2020; Elia et al., 2021; Paul et al., 2021; Strange, 2020; Verbeke, 2020). Supply chain practitioners are being encouraged to redesign their supply chains to proactively limit the disruptions that will be caused by future geopolitical events (Paul et al., 2021).

Pharmaceutical companies are striving to geographically diversify their supply chain through strategies such as reshoring (Winterhalter, 2022). Reshoring is the practice of returning or relocating a company's business practices to their country of origin (Morales Contreras & Leporati, 2020). This strategy has undergone much discussion in Europe, the United States (US), and India, and there are already examples of companies announcing their reshoring plans. However, there are significant barriers for the implementation of reshoring such as high costs and the lengthy time frame required for companies to build new or upgrade existing API manufacturing facilities (Stark & Botos, 2021). This paper will explore the potential and feasibility of reshoring as a strategy to strengthen API supply chains.

The research objectives for this study are outlined below:

1. *Identify the different stages in the supply chain of medicine.*
2. *Identify the different disruptions and challenges in pharmaceutical supply chain management.*
3. *Identify the factors that influence the location of the production of an API.*
4. *Analyse the impact globalisation and Covid-19 had on the pharmaceutical supply chain.*
5. *Identify ways in which companies can secure their supply chain of active pharmaceutical ingredients.*
6. *Identify the drivers and barriers for reshoring and ways to mitigate barriers.*

In order to meet my research objectives, I will conduct both primary and secondary research. I first will begin with secondary research which will consist of a comprehensive literature review exploring the topic. The literature review will be divided into six sections to explore each subtopic related to the research. I will then use the information gathered in the literature review to guide my primary research which will be in the form of semi-structured interviews with industry professionals. I will interview several professionals working in distinct roles and stages in the pharmaceutical supply chain to get a diverse range of responses that will make my research more objective and accurate. Finally, in the discussion section of this paper, I will analyse and contrast the results obtained in the interview process with the findings from my comprehensive literature review to draw final conclusions and offer recommendations.

The structure of the subsequent sections in this paper is outlined below:

1. *Literature Review*
2. *Methodology*
3. *Results*
4. *Discussion*
5. *Conclusion*
6. *Annex*
7. *Bibliography*

2. Literature Review

This literature review aims to provide a comprehensive overview of the current research on the topic of supply chain management of active pharmaceutical ingredients. The review is structured into six different sections, each focusing on a specific aspect of the topic. Section 2.1 provides a brief introduction of supply chain management in the pharmaceutical industry with the subsequent sections delving into key themes and findings that have emerged from previous research including disruptions and risks in the pharmaceutical supply chain and the redefinition of global supply chains including strategies such as reshoring. To aid in summarising the main findings of each section, a key findings table will be included at the end of each section. The order of the sections is outlined below:

Section 2.1 - Supply Chain Management in the Pharmaceutical Industry
Section 2.2 - Active Pharmaceutical Ingredients
Section 2.3 - Globalisation
Section 2.4 - Disruptions and Risks in the Pharmaceutical Supply Chain – Covid-19
Section 2.5 - Redefinition of Global Supply Chains – Reshoring, Nearshoring, and other Solutions
Section 2.6 - Public Policy

2.1 - Supply Chain Management in the Pharmaceutical Industry

In this section, I will provide an overview of supply chain management in the pharmaceutical industry including information about the key players in the industry and distinct phases in the supply chain. The Council of Supply Chain Professionals (CSCMP) definition of supply chain management states that it "encompasses the planning and management of all activities involved in sourcing and procurement, conversion, and all logistics management activities. Importantly, it also includes coordination and collaboration with channel partners, which can be suppliers, intermediaries, third party service providers, and customers. In essence, supply chain management integrates supply and demand management within and across companies." (Council of Supply Chain Professionals Supply Chain Management Definitions and Glossary, 2010). Another definition states that "Supply chain management consists of developing a strategy to organise, control, and motivate the resources involved in the flow of services and materials within the supply chain" (Krajewski et al., 2007). It is the active management of supply chain activities to maximise customer value and to achieve a sustainable competitive advantage (Handfield, 2021). Supply chain management includes activities such as product development, planning, sourcing, production, logistics, returns, and information systems required to coordinate these activities (Handfield, 2021).

In supply chain management, organisations involved in the supply chain are referred to as either upstream or downstream. The upstream supply chain refers to all activities related to the company's suppliers whereas downstream supply chain refers to post-manufacturing activities such as the distribution of products to consumers. In other words, the upstream supply chain can be referred to as "supply" and downstream supply chain can be referred to as "demand" (Unival Logistics, 2022). These organisations are interconnected through different flows such as product or material flows, information flows, financial flows, and intangible flows (Morales Contreras et al., 2021). The product/material flow is the flow of the physical product from the supplier to the consumer. It is generally unidirectional unless the customer returns the product (KPA, 2022). The information flow is an essential part of the supply chain as it can be characterised as an enabler of improvement and collaboration (Power & Bahri, 2004). It has been regarded as the most important flow in a supply chain as without the information flow there is no product flow (Yousefi & Alibabaei, 2015). This is a bi-directional flow as it includes the flow of information from the supplier to the customer and from the customer back to the supplier (KPA, 2022). The type of information shared can include product data, pricing, inventory levels, supplier and distributor information, delivery status, documents, financial

information (Bsaikrishna, 2016). This flow is essential for responding to customer demand and increasing overall customer satisfaction (Singh, 1996). The financial flow involves the movement of money from the customer to the supplier. Similar to product or material flows, this is generally unidirectional except in the case of returns (KPA, 2022). Intangible flows can include risks, innovation, and personal relations (Morales Contreras et al., 2021).

There are numerous benefits to supply chain management. Effective supply chain management can produce competitive advantages such as unique products and services, faster research and development (R&D) cycle times, superior quality, cost competitiveness, shorter order cycles, flexible customer response, enhanced delivery performance, better asset management, increased cash-to-cash velocity, and superior channel relationships (Fawcett et al., 2008). These competitive advantages lead to higher customer satisfaction and service which is essential for long-term customer retention.

The global pharmaceutical industry is responsible for the research, development, production, and distribution of medications (Mikulic, 2022). It is an industry that has experienced significant growth over the past two decades with revenue in 2022 adding up to 1.48 trillion USD (Mikulic, 2022). Pharmaceutical supply chains should provide the right quantity of medicines, with an acceptable quality, to the correct place and correct customers, at the right time and with optimum cost to be consistent with health system's objectives which also benefits stockholders (Kaufmann et al., 2005). Any flaw in the supply chain in this industry can have serious effects and threaten patient's life through hindering access to medicines (Schneider et al., 2010). In this way, supply chain management in this industry is crucial to ensure the health and wellbeing of patients. Pharmaceutical supply chain resilience is a formidable challenge in nearly every country all over the world (Bhatia et al., 2013).

According to Shah (2003), there are several different key players in the pharmaceutical industry. These include:
   i.   Large, research and development-based multinationals which focus on providing branded products. They tend to have multiple manufacturing sites all over the world.
   ii. Large generic manufacturers that produce products whose patent has expired.
   iii. Local manufacturing companies that produce both branded and generic products under licence or contract solely in their home country.
   iv. Contract manufacturing organisations (CMOs) who do not have their own product portfolio but instead produce active pharmaceutical ingredients, intermediates, or final products through providing outsourcing services to other pharmaceutical companies.
   v.   Drug discovery and biotechnology companies that often have few resources and are new startups with little manufacturing capacity.

Pharmaceutical supply chains differ depending on many distinct factors and involve a number of players such as government agencies, hospitals, manufacturers, primary and secondary distributors, pharmacies, and research organisations (Spoto, 2021). The lifecycle of a pharmaceutical product begins with the drug development process which is a five-step procedure that results in a registered new drug (FDA, 2018). On average this process can take twelve years but for newer areas of medicine, it can take up to thirty years (Amoranitis, 2023). The process includes discovery and development of the drug, preclinical research to answer basic safety questions, clinical research where drugs are tested on people to ensure safety and efficacy, market approval and launch, and post-market safety monitoring (FDA, 2018). Once the drug is registered, patent protection begins, and the manufacturing process must be established to maximise efficiency (Shah, 2003). After this, manufacturing, and distribution follow (Shah, 2003).

Shah (2003) states that in general, a typical pharmaceutical supply chain will consist of one or more of the following stages:

i. Primary manufacturing
ii. Secondary manufacturing
iii. Warehouses/distribution centres
iv. Wholesalers
v. Providers – pharmacies and hospitals

The manufacturing of a pharmaceutical product is divided into two stages – primary manufacturing and secondary manufacturing. Primary manufacturers are responsible for the production of the active pharmaceutical ingredient which can also be known as the "drug substance." The process normally involves either several chemical synthesis and separation stages to build up the molecules involved, or fermentation and production recovery and purification for biochemical processes (Shah, 2003). Figure 1 presents the five-step process of the production of an API. The production process of an API starts with Key Starting Materials (KSM) which are also known as API Starting Materials. According to the European Medicines Agency (2000), "an API Starting Material is a raw material, intermediate or an API that is used in the production of an API and that is incorporated as a significant structural fragment into the structure of the API." The API intermediate (also known as drug intermediate) is a material produced during the intermediate steps of synthesis that requires further molecular change or processing to become a final API (Government of India, 2020). The final API intermediate is then produced when the API intermediate undergoes synthetic transformation which is the formation or breaking of covalent bonds (WHO, 2023). The crude API is obtained after a series of purification steps such as filtration, crystallisation and drying, and is the impure form of the API (Ortega Diego, 2015). The final API is the purified and isolated form of the API that meets the quality specifications and purity requirements for use in pharmaceutical formulations (Ortega Diego, 2015). Companies often use contractors to manufacture some or all stages of the production of active pharmaceutical ingredients which allows them to focus on the more profitable discovery and development activities (Shah, 2003).

*Figure 1 - The Manufacturing Process of an Active Pharmaceutical Ingredient*
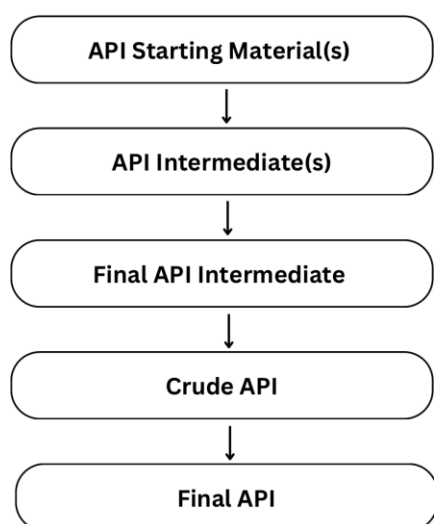
Source: Adapted from Ortega Diego (2015)

Secondary manufacturing is concerned with combining the active pharmaceutical ingredient produced during primary manufacturing and adding excipients to further process the final product in its finished dosage form which is ready for consumption. A product sold in pill form would usually undergo processes such as dry/wet granulation, direct compression, and quality control (Roy, 2011). The primary and secondary manufacturing sites are often in different geographical locations and transportation is required to ship the active pharmaceutical ingredient to the secondary manufacturing site and then to warehouses or distribution centres (Shah, 2003). The product must then be packaged which can be done by the secondary manufacturer or a third party. Packaging is divided into primary and secondary packaging. Primary packaging consists of the materials that are in direct contact with the finished pharmaceutical product (Stark et al., 2022). This can include tablet blisters, ampoules, vials, or pre-filled syringes (Stark et al., 2022). Secondary manufacturing consists of placing the primary package into the outer packaging that contains the printed data and branding, and also includes the package insert (Stark et al., 2022).

Once the pharmaceutical products have been manufactured and packaged, wholesale distributors who are either primary or secondary distributors then purchase massive quantities of these drugs from the manufacturers and distribute these products to providers which can include pharmacies, hospitals, and other medical facilities (Spoto, 2021). Wholesalers play a significant role in this process as they are typically exceptionally large. In the UK, 80% of the demand for pharmaceutical products is sold through wholesalers with three larger players dominating the sector (Shah, 2003). Wholesalers/Distributors store the pharmaceuticals using inventory tracking systems in optimum conditions for their later use. When distributors receive the purchase orders from providers, they prepare and ship the products to them (Spoto, 2021). Providers handle the pharmaceuticals just before they reach the final consumer. The providers store, manage and safely dispense the products to the consumers (Spoto, 2021). Figure 2 presents a diagram of the pharmaceutical supply chain.

Figure 2 - The Pharmaceutical Supply Chain
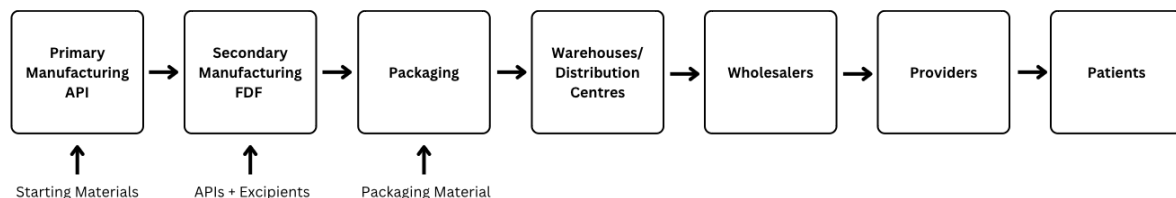
Source: Own elaboration based on Shah (2003)

In terms of the four supply chain flows, the product/material flow is the flow of the medicine throughout the supply chain from the raw materials to the finish dosage form delivered to the consumer. As pharmaceutical supply chains are complex and involve several players, adequate information flow is essential to the functioning of the supply chain. The information flow can be managed through supply chain information systems (SCISs) that coordinate information between internal and external customers, manufacturers, distributors, and other players in the supply chain (Yousefi & Alibabaei, 2015). These systems can be divided into four layers which include transaction processing systems, management control systems, decision analysis systems and strategic planning systems (Yousefi & Alibabaei, 2015). In terms of the financial flow, a 2017 study in the US found that for a hypothetical $100 dollars spent on prescription drugs by a consumer, manufacturers received $58 dollars whereas providers, wholesalers and other players collectively received $42, $8 of which is

net profit (Sood et al., 2017). For intangible flows, the pharmaceutical industry places a strong importance on innovation. This is largely focused on the discovery and development phase of the life cycle of a pharmaceutical product but flows throughout the supply chain through improvements in technology and processes. Table 1 below provides a summary of the key points discussed in this section. The following section will provide an overview of active pharmaceutical ingredients.

Table 1 - Supply Chain Management in the Pharmaceutical Industry

> • In the pharmaceutical industry, supply chain management is crucial to ensure the health and well-being of patients.
>
> • Pharmaceutical supply chains should provide the right quantity of medicines with an acceptable quality to the correct place and correct customers at the right time and with optimum cost to be consistent with health system's objectives which also benefits stockholders.
>
> • The pharmaceutical industry has a several different key players including large multinationals, large generic manufacturers, local manufacturing companies, contract manufacturers, and drug discovery and biotechnology companies.
>
> • Pharmaceutical supply chains are complex and can differ depending on many distinct factors and involve a number of players such as government agencies, hospitals, manufacturers, packagers, primary and secondary distributors, pharmacies, and research organisations.
>
> • The production of an API includes five stages – starting material(s), API intermediate(s), final API intermediate, crude API, and final API.
>
> • A typical supply chain consists of primary manufacturing, secondary manufacturing, packaging, warehouses/distribution centres, wholesalers, and providers.

Source: Own elaboration based on literature review

2.2 - Active Pharmaceutical Ingredients

This section provides an overview of what active pharmaceutical ingredients are, the different ways they can be segmented, and provide insights into the API market. There are two ingredients that make up a medication – APIs and excipients. APIs are the major or active component in a medication that produce the required health effect on the body to treat a condition. They have pharmacological activity used to diagnose, cure, mitigate, and treat a disease (Kumar et al., 2022). Excipients are the secondary component in a medication which are chemically inactive but serve as a medium to deliver the API. Excipients have a wide variety of functions which include providing volume, flavour, colour, stability and facilitating absorption of the drug. Active pharmaceutical ingredients are divided into two different types – synthetic and natural APIs. Synthetic chemical APIs can also be known as small molecules and take up the majority of the pharmaceutical market. In 2021, the synthetic API market accounted for a revenue share of 72.6% of the overall market (Grand View Research, 2022). This is due to the higher availability of the required raw materials and the simpler production process of these molecules (Grand View Research, 2022). Natural APIs are used in making biologics and although they are a minority in the market, the market for biologics is continually increasing. This is attributed to the increasing demand for biopharmaceuticals, the higher efficiency of these molecules and the increase in investment in research and development for these products (Grand View Research, 2022).

The high revenue of these products is also a driver for companies to invest in the research and development of these products (Grand View Research, 2022).

According to one report, the active pharmaceutical ingredients market in 2021 was valued at approximately $177 billion and is forecasted to reach $258.60 billion by 2027, signifying a 7.5% compound annual growth rate (CAGR) in the 5-year period from 2022-2027 (Mordor Intelligence, 2021). Another report valued the global active pharmaceutical ingredients market to be $222.4 billion in 2022 and forecasts a 5.9% compound CAGR from 2023 to 2030 (Grand View Research, 2022). The key factors explaining this market growth are the increase in drug research and development activities, the increasing importance of generic products and also the increasing uptake of bio pharmaceuticals (Mordor Intelligence, 2021). The increasing number of chronic diseases such as cardiovascular diseases and cancer are also expected to increase the demand for drugs in the coming years (Grand View Research, 2022). Advancements in active pharmaceutical ingredient manufacturing can also be attributed to the growth rate in the market (Grand View Research, 2022). Both reports identified the positive impact that the Covid-19 pandemic had on the industry with a greater demand for pharmaceutical products to treat the symptoms of the disease (Grand View Research, 2022). Furthermore, the growth in demand for active pharmaceutical ingredients can also be related to the global aging population. As life expectancies continue to rise, the requirement for medicines to treat age related illnesses also increase (Grand View Research, 2022).

The active pharmaceutical ingredients market can be segmented by business mode (captive API and merchant API), by synthesis type (synthetic and biotech), by drug type (generic and branded), by application (oncology, cardiology, pulmonology, ophthalmology, orthopaedic, neurology etc and by geography (Mordor Intelligence, 2021). The captive market for active pharmaceutical ingredients is the market of APIs produced internally by pharmaceutical companies whereas the merchant market is the market of APIs produced by third parties i.e., CMOs. In 2022, the captive API market segment accounted for 51.5% of the revenue share for the segment (Grand View Research, 2022). This number is expected to grow over the coming years due to the availability of raw materials and extensive investments by major players in the industry to develop high-end manufacturing facilities (Grand View Research, 2022). However, the popularity of the merchant market for APIs cannot be ignored as API outsourcing allows companies to dedicate resources to research and development instead of costly manufacturing facilities and the labour force (Grand View Research, 2022).

The top players in the active pharmaceutical ingredients market include Teva Pharmaceutical Industries Ltd, Sun Pharmaceutical Industries Ltd, Novartis AG, Pfizer Inc., Merck & Co., Inc, AbbVie, Inc., Bristol-Myers Squibb Company, Dr. Reddy's Laboratories Ltd., Cipla, Inc. and Mylan NV (Mordor Intelligence, 2021). It is a highly competitive and fragmented market, and it includes several key players globally (Mordor Intelligence, 2021). The active pharmaceutical market is a global market with production and demand worldwide. In 2022, North America accounted for the largest revenue share with 38% of overall revenue and is forecasted to continue to maintain its lead over the next 8 years (Grand View Research, 2022). Asia Pacific accounts for the fastest growing CAGR of 7.1% from 2023 – 2030 with India and China being the most significant countries in this region largely due to their low cost and high-volume production of APIs (Grand View Research, 2022). Europe is also expected to witness significant growth between 2023-2030 due to an increase in research funding and the local presence of key players in the industry (Grand View Research, 2022). Europe largely differentiates itself in the market through investment in specialised and often highly potent APIs.

According to the 2022 Convention on Pharmaceutical Ingredients (CPHI) Annual Report, the US, India, Germany, and China have been forecasted to have the highest growth potential in the pharmaceutical market over the coming year (CPHI, 2022). This is a historical change as China and India have been dominating this category over the previous years (CPHI, 2022). European countries such as Germany,

the UK, Italy, and France experienced significant growth potential increase in scores in comparison to 2021 with exponential percentage changes in scores between 23.2% and 35.2% in these countries (CPHI, 2022). This may signify a shift in the global market over the coming years. The report stated that all countries improved their potential growth scores which suggests positive prospects for 2023 (CPHI, 2022). The overall competitiveness rankings for the pharmaceutical industry in 2022 sees that the USA, India, United Kingdom (UK), Germany, and China are the top 5 most competitive countries in the report with the UK moving from 8th place to joint 3rd place in just one year (CPHI, 2022).

The report also identifies the countries with the highest rankings for API Manufacturing Quality with the top three being Germany, the US, and the UK (CPHI, 2022). The report states that China and India have experienced high improvements in their scores with India especially receiving a 15% increase in API manufacturing quality (CPHI, 2022). This is the first time that an emerging pharmaceutical economy has scored on par with major western pharmaceutical nations (CPHI, 2022). India is now placing level with Switzerland and Japan in terms of API manufacturing quality (CPHI, 2022). The United States Pharmacopeia (USP) has reported that in 2022, over 80% of the APIs used in essential medicines were manufactured overseas, with Indian manufacturing sites dominating. According to the USP, of the 342 manufacturing facilities globally with more than ten active US-approved APIs, more than half of these facilities are based in India. Furthermore, of the manufacturing facilities worldwide with more than thirty active US-approved products, India accounts for 65% of these facilities (Jimenez, 2022). China similarly improved its API manufacturing reputation this year seeing a large 25% improvement in 2022 putting itself in line with the manufacturing quality scores of both France and Italy (CPHI, 2022).

There are many regulatory mechanisms used to establish the quality, safety, and efficacy of active pharmaceutical ingredients. A Drug Master File (DMF) is a document voluntarily submitted to the Food and Drug Administration (FDA) in the U.S. that can be used to provide confidential, detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of drugs (FDA, 2005). Submitting a DMF allows the API manufacturer to maintain control over the confidential information while still allowing drug manufacturers to reference this information in their own drug application (FDA, 2005). This allows companies to expedite the drug application review process as they do not need to duplicate information and documentation (FDA, 2005). The equivalent to the DMF in Europe is the ASMF (Active Substance Master File).

A CEP is a certificate that proves that the quality of an API complies with the quality standard defined by the European Pharmacopeia (ECA Academy, 2018). It is a certificate issued by the European Directorate for the Quality of Medicines and HealthCare (EDQM) to the API manufacturer as part of the market authorisation process (Badwy, 2022). The information submitted in the CEP is strictly confidential (Badwy, 2022). Good Manufacturing Practices (GMP) are defined as "a system of manufacturing that guarantees reproducibility of product quality to set specifications" (Badwy, 2022). It is the main standard of quality worldwide in the pharmaceutical industry and is defined as the minimum standards that manufacturers must meet (Keles, 2022). Although only four regulatory mechanisms are described above, there are multiple other mechanisms implemented in the pharmaceutical industry to ensure the safety, quality, and efficacy of active pharmaceutical ingredients. Table 2 below outlines the key points discussed in this section. The following section examines the effects of globalisation on the pharmaceutical industry.

Table 2 - Active Pharmaceutical Ingredients

- Active pharmaceutical ingredients (APIs) and excipients are the two ingredients that make up a medication.

- APIs are the major or active component in a medication that produce the required health effect on the body to treat a condition.

- Synthetic chemical APIs, also known as small molecules, take up the majority of the revenue share of the pharmaceutical market.

- The active pharmaceutical ingredients market in 2021 was valued at $177.05 billion and is forecasted to reach $258.60 billion by 2027.

- The main factors that explain this market growth are the increase in drug research and development activities, the increasing importance of generic products, the increase in chronic diseases, the advancements in API manufacturing, the global aging population, and the increasing uptake of biopharmaceuticals.

- The active pharmaceutical market is highly competitive and fragmented and includes many top players globally.

- The North American market accounted for the largest revenue share, with 38% of overall revenue in 2022, followed by Asia Pacific with the fastest growing CAGR of 7.1% from 2023-2030.

- The USA, India, Germany, and China have been forecasted to have the highest growth potential in the pharmaceutical market over the coming year.

- Germany, the USA, and the UK have ranked highest for API Manufacturing Quality.

- India and China experienced high increases in their API Manufacturing Quality score over the past year.

- European countries have experienced a significant increase in growth potential scores of between 23.2% and 35.2% in comparison to 2021. This may signify a shift in the global market over the next few years.

- Regulatory Mechanisms such as CEP, DMF, and GMP help ensure the safety, efficacy, and quality of APIs.

Source: Own elaboration based on literature review

2.3 - Globalisation

This section examines the impact of globalisation on the pharmaceutical industry. Through an analysis of relevant literature, I explore the changes, causes, effects, and supply chain risks associated with this trend, providing valuable insights into its transformative effects. Globalisation has had a significant impact on the pharmaceutical industry. In 2019, the FDA reported that although the United States is a world leader in drug discovery and development, it is no longer in the forefront of drug manufacturing (Woodcock, 2019). Historically in the US drug manufacturing was domestically based but this has changed over the past few decades (Woodcock, 2019). This is of particular significance for the manufacturing of active pharmaceutical ingredients. As shown in Figure 3, as of August 2019, only 28% of the manufacturing facilities producing APIs to supply the US market were based in the US (Woodcock, 2019). In 2021, India accounted for 48% of all active API DMFs with Europe accounting for 22%, China 13% and the US 10% (Raghavendran & Christian, 2022).

Figure 3 - Total Active API DMFs by Country as of 2021
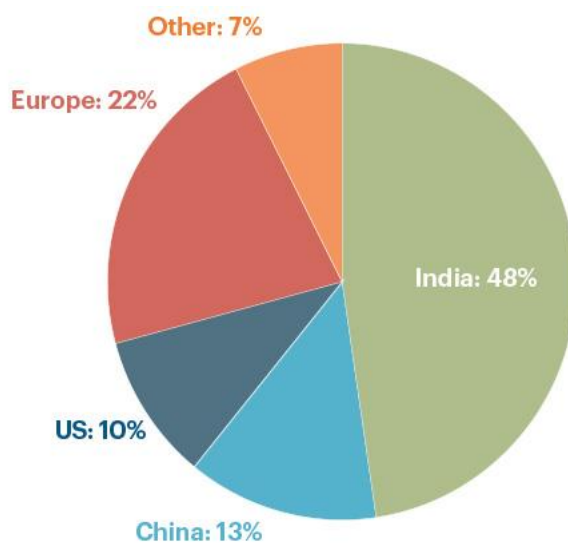
Source: US Pharmacopeia Medicine Supply Map cited by Raghavendran et al (2022)

Since the 1990's the production of active pharmaceutical ingredients has been moving from western countries to developing countries such as India and China (Bumpas & Betsch, 2009). Much of this growth has been driven by low production costs in these countries but other factors include fewer environmental regulations, large-tiscale manufacturing and low barriers to market entry (Bumpas & Betsch, 2009). Figure 4 presents active API drug master files by year of filing and country of manufacture between 2000 and 2021. A 2009 study stated that if a standard western API company has an average wage index of one hundred, this index is as low as ten for an Indian company and eight for a Chinese company (Bumpas & Betsch, 2009). China has lower electricity, coal, and water costs and is involved in a network of raw materials and intermediary suppliers which translates to lower shipping and transaction costs for raw materials (Woodcock, 2019). A 2011 report by the FDA stated that API manufacturing in India can reduce costs by between 30% and 40% for European and US companies (FDA, 2011).

Figure 4 - Active API Drug Master Files by Year of Filing and Country of Manufacture (2000-2021)
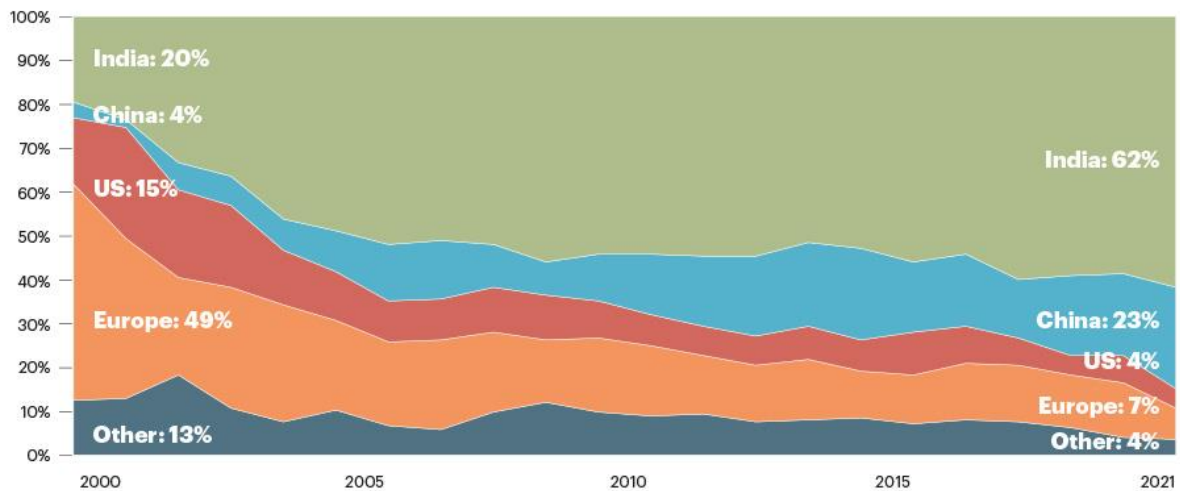
Source: US Pharmacopeia Medicine Supply Map cited by Raghavendran et al (2022)

Europe has similarly experienced a shift in API production due to globalisation. In 2020, only 33% of CEPs required in Europe were held by European manufacturers (Pro Generika, 2020). Asia held over 60% of all CEPS with Chinese and Indian manufacturers holding over 50% of all CEPs (Pro Generika, 2020). There are no CEPs available in Europe for 93 APIs required in the region (Pro Generika, 2020). Furthermore, more than half of all APIs only have between 1-5 CEPs worldwide, signifying that there are very few manufacturers (Pro Generika, 2020). This puts Europe in an extremely precarious position in the event of a disruption in the supply chain.

Between 2000 and 2020, Asia has significantly outperformed Europe and grown at a much greater rate in terms of API manufacturing (Pro Generika, 2020). During this time frame, Asian manufacturers grew their number of CEPs from 183 to 2369 whereas European manufacturers only experienced an increase from 348 to 1260 CEPs (Pro Generika, 2020). The growth in CEPs in both regions can be explained by the increasing number of patent expirations which has driven an increase in generic APIs.

In terms of the types of APIs produced in these regions, Europe presently focuses on the production of complex, smaller-volume APIs (Pro Generika, 2020). These APIs have technologically complex production processes and strict quality requirements (Pro Generika, 2020). European manufacturers tend to have larger API portfolios in comparison to Asia as Asian manufacturers tend to have a smaller API portfolio with larger production volumes (Pro Generika, 2020). There are strong drivers for the production site selection in this industry with APIs being produced either mainly in Europe or Asia with very few APIs that have an even distribution of production sites in both Asia and Europe (Pro Generika, 2020). In general, older APIs that have been historically manufactured in Europe have experienced a slow migration to Asia whereas newer APIs are dominated by Asian manufacturers (Pro Generika, 2020).

India and China have different areas in which they focus their production of pharmaceuticals. India has become known as the "pharmacy of the world." Previously India focused more on the production of APIs but has now become a larger producer of finished dosage forms (FDF) medicine. It is the world's largest generic medicine provider and has a strong reliance on China for the production of APIs (Kanwal, 2022). It is estimated that 70% of APIs that India needs for the manufacturing of generic medicine comes from China (Panda, 2022).

The globalisation of the active pharmaceutical ingredient industry has provoked significant challenges and risks. Globalisation has incited difficulties in ensuring the quality and adherence to Good Manufacturing Practices of APIs and has led to an increase in falsified and counterfeit medicines. In more developed countries, counterfeit medicines are less prevalent due to strict legislation, stronger institutions, and more efficient regulatory control (Farmaki et al., 2012). Globalisation has complicated the pharmaceutical supply chain resulting in increased quality issues in every stage in the supply chain. Furthermore, globalisation has provoked supply chain vulnerabilities due to the over dependence of APIs in certain regions. Covid-19 has exposed this vulnerability to supply shifts in demand, supply shocks, changing regulations and over-reliance on key suppliers (Hariharan et al., 2022). Table 3 summarises the key points from this section. The following section explores the different disruptions and risks in the pharmaceutical supply chain.

Table 3 - Globalisation

• The globalisation of the pharmaceutical industry has led to a shift in active pharmaceutical ingredient (API) manufacturing from western countries to developing countries, particularly India and China.
• This shift is due to lower production costs, fewer environmental regulations, and low barriers to market entry in developing countries.
• Between 2000 and 2020, Asian manufacturers have grown their number of API certificates of suitability (CEPs) at a much greater rate than European manufacturers.
• Europe focuses on the production of complex, smaller-volume APIs, whereas Asian manufacturers tend to have a smaller API portfolio with larger production volumes.
• The globalisation of the API industry has led to difficulties in ensuring quality, adherence to Good Manufacturing Practices (GMP), and an increase in falsified and counterfeit medicines.
• There is an over-dependence on certain regions for the supply of APIs, which can create supply chain vulnerabilities, as highlighted by the Covid-19 pandemic.

Source: Own elaboration based on literature review

2.4 - Disruptions and Risks in the Pharmaceutical Supply Chain – Covid-19

This section examines the risks and disruptions that affect the pharmaceutical supply chain, with a focus on the impact of Covid-19. As the pandemic has exposed vulnerabilities in the supply chain, understanding these challenges is crucial for developing effective strategies to mitigate future disruptions and ensure continued access to critical medicines.

There are a multitude of different types of disruptions and risks that can affect the pharmaceutical supply chain and cause drug shortages. Drug shortages have been recognised globally as a key issue to be resolved in the pharmaceutical industry for many years now and have been prevalent in the industry long before the Covid-19 pandemic. The European Parliament announced in a statement in 2020 that drug shortages in the European Union (EU) had increased 20-fold between 2000 and 2018 (Colin-Oesterlé, 2020). As of the 26th of March 2023, in Spain alone there were 746 products with active supply problems (AEMPS, 2023). Drug shortages can have severe effects on patients causing adverse drug reactions, drug errors, increased hospitalisation times, higher patient out of pocket

costs, reduced quality of treatment, and in some cases death (Phuong et al., 2019). The causes of drug shortages are diverse and include supply issues, demand issues, and regulatory issues (Shukar et al., 2021). Supply issues can include manufacturing problems, shortage of raw materials, logistics and business problems (Shukar et al., 2021). Demand issues can include just-in-time inventory, increases in product demand, seasonal demand, and unpredictable demand (Shukar et al., 2021). Geopolitical events or trends such as Covid-19, the energy crisis, the war in Ukraine and high inflation rates can exacerbate drug shortages (MSSG, 2023).

The Covid-19 pandemic highlighted the gaps in pharmaceutical supply chains through exposing the dependency that the industry has on the production of APIs in China and India. Covid-19 mainly affected the pharmaceutical industry in three ways – through price increases, increases in pharmaceutical demand, and disruptions in the pharmaceutical supply chain (Data Bridge Market Research, 2021).

The outbreak of the Covid-19 pandemic resulted in lockdowns all over the world. China was the epicentre of this outbreak and introduced strict measures early on to stop the spread of the virus (Sharma et al., 2020). Pharmaceutical manufacturing halted and exports drastically declined affecting the imports in other countries (Sharma et al., 2020). China's lockdown measures had a massive impact on the pharmaceutical industry affecting APIs, raw materials, shipments, procurements, FDF drugs and much more (Sharma et al., 2020). As the largest manufacturer of APIs, China's lockdown measures produced a knock-on effect on the industry and especially affected the pharmaceutical industry in India. India depends on China for 70% of the active pharmaceutical drugs required to produce FDF drugs and as the world's largest generic drug manufacturer, India plays a significant role in the supply of generic drugs worldwide (Panda, 2022). Due to these disruptions, India restricted the export of APIs outside of the country to ensure that they had sufficient APIs for their own domestic demand for drugs (Nawrat, 2022). The Directorate General of Foreign Trade in India imposed these restrictions on the export of thirteen APIs and thirteen formulations that are made from these APIs (Yadav, 2020).

As India and China are the countries in which there is the highest production of APIs and intermediates, there was a significant impact on the pricing of these products as the supply chain was disrupted (Data Bridge Market Research, 2021). In India, the cost of APIs and their intermediates increased by up to 40-50%, particularly for medicines such as paracetamol, penicillin, and anti-asthma drugs (Data Bridge Market Research, 2021). The price of the raw material needed for the production of penicillin increased in price by 40% in just a month (Saha & Mallik, 2020). Furthermore, there was an increase in price between 13-18% for the APIs used in antibiotics such as Azithromycin, Doxycycline, Amikacin, Ornidazole, and Dexamethasone Sodium which India imports from China (Saha & Mallik, 2020). The number of air shipments decreased during this time, provoking an increase in the cost of shipment by 300% which had a knock-on effect in the price of APIs and intermediates (Data Bridge Market Research, 2021).

In terms of shortages, it has been estimated that 43% of acute care medicines such as antibiotics, sedatives and blood thinners ran in low supply during the peak of the crisis (Silverman, 2020). In October 2020, twenty-nine out of the forty drugs used to combat the coronavirus were in short supply across the U.S. and Europe (Silverman, 2020). The pandemic slowed the production of APIs through supply chain disruptions that led to delays in the availability and shortages. In early 2019, shipments from Chinese CMOs to the US took less than 50 days (GEP, 2022). In January 2022, the delivery time hit a record high of 113 days (GEP, 2022).

Ultimately, the Covid-19 pandemic did not seriously impede the production and shipment of pharmaceutical products (Mullin, 2020). This was largely due to inventories of backup supplies of ingredients and the intervention of governments around the world (Mullin, 2020). However, it did

alert world leaders and pharmaceutical companies around the world of the serious vulnerability there is in the pharmaceutical supply chain and has inspired them to make changes to this supply chain (Mullin, 2020). In the following section, I will discuss the different strategies that can be undertaken by pharmaceutical companies to strengthen supply chains and ensure the continued access to critical medicines. In Table 4 below, there is a summary of the key points discussed in this section. The following section explores solutions and possible strategies to minimise the disruptions and risks outlined in this section.

Table 4 - Disruptions and Risks in the Pharmaceutical Supply Chain - Covid-19

• Drug shortages are a growing problem in the pharmaceutical industry and can cause adverse drug reactions, drug errors, increased hospitalisation times, higher patient out of pocket costs, reduced quality of treatment and death.

• Drug shortages can be caused by supply, demand, and regulatory issues.

• The Covid-19 pandemic highlighted the dependency of the pharmaceutical industry on the production of APIs in China and India.

• Covid-19 affected the pharmaceutical industry through price increases, increased demand, and disruptions in the supply chain that included shortages and delays in production and shipment.

• China's lockdown measures had a knock-on effect and made a massive impact on the pharmaceutical industry, especially on APIs, raw materials, shipments, and FDF drugs.

• India was heavily affected by China's lockdown measures causing the country to restrict the export of 13 APIs and 13 FDFs produced from these APIs.

• The supply chain disruptions resulted in an increase in the price of APIs and their intermediates.

• Acute care medicines ran in low supply during the peak of the crisis.

• Inventories of backup supplies of ingredients and government intervention prevented serious impediments in the production and shipment of pharmaceutical products.

• The pandemic alerted world leaders and key players in the pharmaceutical industry of the vulnerability in the pharmaceutical supply chain, inspiring changes.

Source: Own elaboration based on literature review

2.5 - Redefinition of Global Supply Chains - Reshoring, Nearshoring & Other Solutions

This section analyses the strategies available to companies to strengthen and redefine their global supply chains, with a particular emphasis on reshoring. Drawing on both academic research and real-world examples from the pharmaceutical industry, I examine the drivers and barriers to this approach, as well as other potential solutions.

The disruptions created by the Covid-19 pandemic has been a trigger for the redefining of global supply chains (Morales-Contreras et al., 2021). Many academics believe that Covid-19 will undermine the "Global Value Chain" – a key trademark of globalization and make value chains more regional or domestic (Baldwin & Evenett, 2020; Baraldi et al., 2022; Enderwick and Buckey, 2020; Elia et al., 2021; Paul et al., 2021; Strange, 2020; Verbeke, 2020). Supply chain practitioners are being encouraged to redesign their supply chains to proactively limit the disruptions that will be caused by future geopolitical events (Paul et al., 2021). Strategies such as shortening value chains, building local sourcing capacities, encouraging key suppliers to operate close to production plants and diversifying source markets are all under discussion (Paul et al., 2021). It has provoked pharmaceutical companies to strive to reduce their reliance on Chinese suppliers and become more API independent (Winterhalter, 2022). Pharmaceutical companies are striving to geographically diversify their supply chain through strategies such as reshoring (Winterhalter, 2022). Reshoring is the practice of returning or relocating a company's business practices to their country of origin (Morales Contreras & Leporati, 2020). Reshoring which is also commonly known as onshoring or backshoring is a practice that signifies the reversal of globalisation and outsourcing. Another strategy that has also been under some consideration is nearshoring – which is the relocation of a company's business practices to a country near to their country of origin (Morales Contreras & Leporati, 2020).

Reshoring is a practice that has been highlighted as one that could build more secure supply chains for pharmaceutical companies that produce APIs. The main drivers for this practice are increased flexibility, quality, and the importance of proximity to specific markets/end-users (Raza et al., 2021). Reshoring can also better align supply chain strategies to corporate priorities and value propositions such as heritage and restored brand values or higher environmental sustainability (Robinson & Hsieh, 2016). Reshoring allows companies to exploit economies of scale, avoid trade barriers and tariffs when re-importing goods, and take advantage of nationalist and populist policies (Elia et al., 2021). Baraldi *et al*. (2022) discusses the different benefits of the strategy for different stakeholders. For hospitals and patients, the benefits can include fewer shortages of drugs, reduced indirect costs of care caused by reduced hospitalisation time and less money and time used to source alternative treatments, reduced patient suffering, and reduced pressure on antibiotic resistance as the optimal antibiotics are available (Baraldi et al., 2022).

Reshoring has undergone much discussion in Europe, the US, and India and there are already examples of companies announcing their reshoring and nearshoring plans. The French multinational pharmaceutical giant Sanofi is one of the world's leading pharmaceutical companies with a large product offering of branded drugs, generics, vaccines, and consumer health products (Mikulic, 2022). In 2020, the company announced its plans to create a new industry leading European company headquartered in France to provide APIs to ensure secure significant API manufacturing and supply capacities for patients in Europe (Sanofi, 2020). The project consisted of creating a standalone company which would combine the company's API commercial and development activities with six of its European API production sites in Italy, Germany, the UK, France, and Hungary (Sanofi, 2020). The company cited the heavy reliance of APIs sourced from Asia and the increasing number of shortages of medicines that critically impact patient care as the drivers for this project (Sanofi, 2020). The new company called EuroAPI is now fully independent with over 200 APIs in its portfolio and boasted sales of €900 million in 2021 (CHEManager, 2022).

AstraZeneca similarly in 2021 announced its nearshoring plans to invest $360 million in a next-generation API manufacturing facility for small molecules in Ireland to strengthen the company's global supply chain network (Kemp, 2021). The programme is expected to significantly reduce commercialisation lead times, costs and introduce more sustainable manufacturing processes (Kemp, 2021). Evonik, one of the world's largest producers of speciality chemicals launched in 2020 the first stage of their European API manufacturing capacity expansion programme through an investment of €25 million in two of their facilities in Germany (Carpenter, 2020). The senior president of Evonik's Health Care business line stated that "The COVID-19 pandemic has amplified the focus of many pharmaceutical companies to have European-based manufacturing sites that can support the production of their life-saving drug products for reliable supply to regional healthcare markets" (Carpenter, 2020). In 2022, US pharmaceutical company Cambrex completed their $50 million expansion of their large-scale manufacturing capabilities in Iowa (Buffery, 2022). This two-year project is set to increase the manufacturing capacity of the site by 30% with an aim to solidify the company's position as the leading US based provider of small molecule APIs (Buffery, 2022).

There are significant barriers for the implementation of reshoring which include high costs and the lengthy time frame required for companies to build new or upgrade existing API manufacturing facilities (Stark & Botos, 2021). Reshoring would signify significant restructuring of supply chains which would be challenging and time-consuming. Another barrier is the local availability of intermediate products needed to manufacture APIs (Sanchez & Muzzio, 2021). If companies neglected to deal with this key point, it would move a country's dependence on foreign sources upstream in the supply chain, continuing the supply chain vulnerability (Sanchez & Muzzio, 2021). There are also barriers such as environmental regulations and regulatory approvals for drug manufacturing facilities, processes, and products (Hicks, 2020).

In order for reshoring to be economically viable and attractive to pharmaceutical companies, policymaker support is required to reduce costs associated with the strategy. In the long term however, companies need to implement cost-reducing production processes innovation such as advanced manufacturing systems (Sanchez & Muzzio, 2021). EY believes that procurement could play an integral role in solidifying reshoring efforts and establishing supply chain resiliency in the US through the formation of strategic partnerships, the leveraging of purchasing consortiums, and establishing contract manufacturing agreements (Stark & Botos, 2021). Strategic partnerships with CMOs who are expanding their US manufacturing facilities would reduce costs for pharmaceutical companies (Stark & Botos, 2021). A purchasing consortium would consist of the collaboration between independent organisations such as pharmaceutical companies with CMOs, contract packaging organisations (CPOs) and third-party logistics providers to increase buyer power and leverage economies of scale on materials, services and solutions offered by vendors (Stark & Botos, 2021). This would increase efficiency for sourcing and manufacturing of pharmaceutical products (Stark & Botos, 2021). The adoption of robust contract manufacturing agreements provides security for CMOs and encourages the strategic national stockpile of essential medicines which proved crucial in the Covid-19 pandemic to buffer the supply chain disruptions (Stark & Botos, 2021). In order to build the capabilities of internal drug manufacturing, Gurvich and Hussain (2020) recommend that universities should collaborate with pharmaceutical companies and redefine the academic curriculum to create a skilled workforce. Another way to make reshoring a viable option is for companies to combine it with technology as robotics-driven automation allows companies to substitute labour with technology which would reduce the costs associated with reshoring (Elia et al., 2021).

While the idea of reshoring has gained popularity in recent years, it is important to acknowledge that not all individuals and organisations support this concept as a viable solution to the vulnerability in the supply chain of APIs. Guinea & Espés (2021) believe that protectionism and autonomy strategies such as reshoring could lead to tit-for-tat reactions globally which would harm international relations and be a lose-lose for all parties. Gereffi (2020) believes that de-globalisation is not a viable solution in the long term. Another article states that manufacturers are focusing more on infrastructure, cybersecurity, digitalisation, and inventory for supply chain resilience rather than reshoring (Turner, 2023). Companies such as Amgen are conducting supply chain risk monitoring, root-cause analysis, performance tracking, and simulation modelling to understand the probability of production slowdown or shutdown (Turner, 2023). Sarkar *et al* (2022) discusses the use of modelling approaches such as mixed-integer programming, stochastic modelling techniques, simulation, and intertwined supply chain modelling to build supply chain resilience. Big data could also be a viable solution that allows companies to examine existing suppliers and identify the best suppliers in terms of costs, efficiency and adaptability to future challenges and disruptions. (Tiwari et al., 2017). This solution can allow companies to identify bottlenecks in production processes, identify the causes and solutions to problems, and make production more efficient, lean, and competitive (Centobelli et al., 2022). Other emerging technologies for consideration include the Internet of Things (IoT), cloud computing, 3-D printing, artificial intelligence (AI), and additive manufacturing (Chowdhury et al., 2021, Yasmin et al., 2020).

Others believe that reshoring is not the solution but rather "right shoring" – having parts of the supply chain situated in the strategic location rather than the entire operation; thus, resulting in the desirable combination of cost, efficiency, and reliability of supply (Turner, 2023). Large API manufacturer Teva diversifies its supply chain through maintaining at least two suppliers for each starting material and intermediate across two locations and uses supplier scoring analytics to select suppliers (Turner, 2023). Diversification allows companies to maintain their international network of production and take advantage of national policies that governments have implemented to recover from the economic crisis caused by Covid-19 (Elia et al., 2021). The use of digital technologies with this strategy can improve coordination and control of partners to manage activities from a distance (Elia et al., 2021).

Javorcik (2020) discussed nearshoring to Eastern European countries who have lower labour costs and a high percentage of pharma exports such as Slovenia and Hungary. Others suggest nearshoring to a large European country who is able to sustain the high costs required for the strategy or to countries who have a "warm manufacturing base" whose production can be easily scaled up (Baraldi et al., 2022).

In the pharmaceutical industry, reshoring and nearshoring strategies have been implemented rarely and mainly for core patented products (Huq et al., 2016; Theyel et al., 2018). Raza *et al.* (2021) stated that drug supply is too complex for a unique solution. Baraldi *et al.* (2022) has seconded this opinion and states that there is no best solution to address pharma supply chains and that both backshoring and nearshoring entail various advantages and disadvantages for different stakeholders. Baraldi *et al*. (2022) believes that it is therefore necessary to develop a more comprehensive approach to evaluate the effectiveness of these strategies in combatting drug shortages. Table 5 below outlines the key points discussed in this section. The following section delves into the role of policymakers in the implementation of reshoring strategies.

Table 5 - Redefinition of Global Supply Chains - Reshoring, Nearshoring and other Solutions

• Covid-19 has triggered the redefining of global supply chains with a move towards regional and domestic value chains.

• Reshoring and nearshoring are two strategies that pharmaceutical companies are considering to diversify their supply chain. Reshoring can be either complete or partial.

• Drivers for reshoring are increased flexibility, quality, and proximity to specific markets/end-users for pharmaceutical companies that produce APIs. Reshoring can also better align supply chain strategies to company values, exploit economies of scale, avoid trade barriers and tariffs, and take advantage of nationalist and populist policies.

• Benefits of reshoring can include fewer drug shortages, reduced indirect cost of care, reduced patient suffering, and reduced pressure on antibiotic resistance.

• Pharmaceutical companies, such as Sanofi, AstraZeneca, Evonik and Cambrex have already announced their reshoring and nearshoring plans to strengthen their global supply chain networks.

• Barriers to implementing reshoring, including high production and relocation costs, lengthy time frame, environmental regulations, regulatory approval, and the availability and location of intermediate products needed to manufacture APIs.

• Policymaker support, cost-reducing production processes innovation, collaborations with universities, and procurement strategies can help make reshoring economically viable and attractive to pharmaceutical companies.

• Procurement strategies include the adoption of contract manufacturing agreements, purchasing consortiums, and strategic partnerships with contract manufacturing organisations which can increase efficiency for sourcing and manufacturing of pharmaceutical products and establish supply chain resiliency.

• Reshoring and nearshoring are not the only strategies that pharmaceutical companies are considering to diversify their supply chain. Other strategies include focusing on infrastructure, cybersecurity, digitalisation, inventory, supply chain risk monitoring, simulation modelling, root-cause analysis, performance tracking, modelling approaches, big data, and other emerging technologies.

• There is a concern that reshoring and nearshoring could affect international relations.

• Some believe that "right shoring" - having parts of the supply chain situated in the strategic location rather than the entire operation is the most efficient strategy.

• Nearshoring to Eastern Europe, large European countries, and countries with a "warm manufacturing base" could also be solutions.

• Drug supply may be too complex for just one solution.

Source: Own elaboration based on literature review

2.6 - Public Policy

This section focuses on the role of public policy as a driver for reshoring. It examines the policies that governments worldwide have undertaken in order to strengthen the pharmaceutical supply chain and ensure the continued access to critical medicines.

Reshoring can be considered as a policy-driven decision by governments to address public-health concerns rather than a business strategy to be employed by individual companies (Fratocchi et al., 2014). Governments all over the world have implemented manufacturing policies to cope with the pandemic with the aim to ensure the continuity of manufacturing operations, to mobilise manufacturing towards critical supplies and to support post-pandemic manufacturing growth (Policy Links, 2020). Governments are now trying to address the vulnerabilities exposed in the pharmaceutical supply chain with a focus on reshoring and nearshoring activities. They are designing policies to transfer global value chains into regional or domestic value chains with a focus on public-health (Elia et al., 2021). There are multiple benefits for governments to implement such strategies. As Baraldi *et al.* (2022) has outlined, these include reduced dependence on countries with political or trade risks, preserved national security, reduced societal costs related to shortages, increased political goodwill due to improved healthcare, employment and GDP, and a better environmental impact due to more stringent environmental regulations in developed countries. However, some drawbacks to such strategies for policymakers are that in order to attract pharmaceutical companies to reshore they would need to increase the price of drugs or invest significantly in company incentives using state funds (Baraldi et al., 2022). In the case of individual countries, there is also the possibility that policymakers may be accused of affecting free market competition in the case of reshoring which could lead to prosecution by bodies such as the EU and cause international trade conflicts with large API exporting countries (Baraldi et al., 2022).

It is largely accepted that government support will play a critical role in the fostering and boosting of manufacturing relocation strategies (Elia et al., 2021). The chief executive officer (CEO) of the pharmaceutical company Sequens stated that "without the support of states, such reshoring will not happen" (Abboud & Peel, 2020). Therefore, it seems that the debate is not whether or not governments should get involved but how they will (Rodrik, 2008).

The European Commission published its Pharmaceutical Strategy for Europe with an aim to secure the supply of medicines across the European Union and to avoid shortages (European Commission, 2020). The European council stated that "achieving strategic autonomy while preserving an open economy as a key objective of the Union" (European Commission, 2020). Measures to achieve this include diversifying production and supply chains, ensuring strategic stockpiling and fostering production and investment in the EU (European Commission, 2020). The EU has proposed to revise pharmaceutical legislation and to launch a structured dialogue with actors in pharmaceutical manufacturing to formulate policy options and propose actions to strengthen the supply of pharmaceuticals in the EU (European Commission, 2020).

In France, President Macron has unveiled an initiative to bring the production of essential medicines back to Europe (Abboud & Peel, 2020). Macron stated that the initiative would start with paracetamol with an aim to reshore production within three years (Abboud & Peel, 2020). The government has made suggestions that they would be open to raising the price that the public health services paid for paracetamol as a financial incentive for the paracetamol API manufacturer Sequens and could also provide loans or other financial support to incentivise the company to move the production of the API to France instead of China (Abboud & Peel, 2020).

In the US, Congressmen Brad Wenstrup and Drew Ferguson introduced an American Made Medicine Act (Spinner, 2022). The bill aims to secure the country's supply chain through reducing the reliance on China and India for pharmaceutical products and create more jobs in the pharmaceutical sector (Spinner, 2022). The bill lowers the tax on income attributed to the domestic manufacturing and sales of API in the country (Spinner, 2022). It also provides tax credits for investments in advanced manufacturing equipment and equipment/property used to meet emission standards (Spinner, 2022).

The Indian government has also implemented policy to reshore the production of APIs and decided to invest $1.3 billion to produce more APIs in the country (Palmer, 2020). The fund includes money for infrastructure and to provide financial incentives to companies of up to 20% of incremental sales value over the next eight years (Palmer, 2020). This strategy has been implemented to reduce India's heavy reliance on China for the supply of APIs used to produce generic drugs. The government hopes that through this investment, India will be able to reclaim some of the market share of APIs that they previously lost to China (Winterhalter, 2022). Table 6 below outlines the key points discussed in this section.

In conclusion, the examination of existing literature in this study has been instrumental in shaping the methodology for the semi-structured interviews. By analysing and synthesising previous research, topics that require further exploration have been identified which guided the interview process. Drawing upon the insights gained from the literature review, the subsequent section will describe the methodology employed for conducting the semi-structured interviews, highlighting their role in achieving the research objectives.

Table 6 - Public Policy

• Reshoring can be considered as a government policy to address public-health concerns rather than a business strategy for individual companies.

• Governments worldwide are taking action to address vulnerabilities in the pharmaceutical supply chain exposed by the COVID-19 pandemic, with a focus on reshoring activities.

• There are multiple benefits for governments to implement such strategies, including reduced dependence on countries with political or trade risks, preserved national security, reduced societal costs related to shortages, increased political goodwill, employment and GDP, and better environmental impact.

• Drawbacks for policymakers are that they may need to increase drug prices or invest significantly in company incentives using state funds to attract pharmaceutical companies to reshore.

• Policymaker support on reshoring activities has a significant impact on the adoption of the strategy.

• The European Commission's Pharmaceutical Strategy for Europe aims to secure the supply of medicines across the EU and avoid shortages by diversifying production and supply chains, ensuring strategic stockpiling, and fostering production and investment in the EU.

• French President Macron has unveiled an initiative to bring the production of essential medicines back to Europe, starting with paracetamol within three years. The government may raise prices or provide financial support to incentivise the API manufacturer Sequens to move production to France instead of China.

• The American Made Medicine Act introduced in the U.S. aims to secure the country's supply chain by reducing reliance on China and India for pharmaceutical products and creating more jobs in the pharmaceutical sector through tax incentives.

• The Indian government is investing $1.3 billion to produce more APIs in the country, providing financial incentives to companies to reduce reliance on China for the supply of APIs and reclaim market shares.

Source: Own elaboration based on literature review

3. Methodology

The methodology section of this thesis describes the method used to collect and analyse qualitative data through semi-structured interviews, which were chosen as a means to delve deeper into the research questions posed in the literature review. This section outlines the procedures followed for participant recruitment, interview design, conduction of interviews, and data analysis, highlighting the actions taken to ensure the accuracy and validity of the research findings.

I decided to conduct qualitative exploratory research in the form of semi-structured interviews. Qualitative data is "a source of well-grounded, rich descriptions and explanations of processes in identifiable local contexts. With qualitative data one can preserve chronological flow, see precisely which events lead to which consequences, and derive fruitful explanations." (Miles et al., 1994). Qualitative research provides data about participant's experiences, perceptions, and behaviour aiming to answer how and why rather than how many or how much (Tenny et al., 2022). I believed that this method was adequate for my research as it would corroborate and add to the information I gathered in doing my literature review by providing further in-depth information from industry professionals. As the research is exploratory, through doing semi-structured interviews I could gather new information from different perspectives.

It is important to use proper techniques when conducting qualitative research to ensure all data is collected in a scientific and consistent manner (Harrell & Bradley, 2009). The development of a semi-structured interview guide requires the identification of prerequisites for using semi-structured interviews, using previous knowledge, formulating the preliminary interview guide, pilot testing the guide and finally presenting the complete semi-structured interview guide (Kallio et al., 2016).

I first did research on how to conduct a semi-structured interview. To make my preliminary interview script, I used the key findings from my literature review and used them to make interview questions. I also used my research objectives to see what information I was lacking from my literature review, and to orient my interview questions to fulfill these objectives. The preliminary interview script is available in Section 7.1 of the Annex. The main purpose of the interviews was to get opinions from experts in the industry about reshoring and to identify other ways companies can secure their supply chain. However, I also had questions referring to the stages in the supply chain of a drug, factors that influence the location of the production of an API, analysing the impact of Covid-19 on the pharma supply chain and to identify trends in the pharmaceutical industry.

I decided to start with broad questions regarding the pharmaceutical supply chain, location decisions, and globalisation and then go into more focused questions about COVID and reshoring. I made sure to make my interview questions open in order to get more detailed responses. I also prioritised my questions to ensure that if the interview were going to go over the allotted time scheduled, I would be able to get the responses I needed from the more important questions.

I decided that I wanted to interview people who had at least five years of experience working in the pharmaceutical industry. This would allow me to get quality responses from individuals who were highly knowledgeable on the subject. I searched for people in distinct roles such as supply chain, procurement, and quality to get a diverse range of responses from people who had different points of view. I also aimed to interview people who were involved in the different stages of the development of a drug such as research and development, primary manufacturing, secondary manufacturing, distribution, wholesale, and providers. By interviewing people who worked in different countries and companies, I would be able to get different viewpoints which would make my research more objective and accurate.

I used my own personal contacts and the contacts of my friends and family to find people to interview. I also asked my interviewees if they could recommend anyone for me to interview. Ultimately, I interviewed six people who were in a variety of different roles, companies, and stages of the supply chain. Table 7 below outlines the interview participants. The interviewees worked in procurement, supply chain, or quality and either worked in Spain or Ireland. They also worked in distinct stages of the supply chain – research and development, primary manufacturing, secondary manufacturing, distribution, and wholesale. I chose these interviewees as they were willing to be interviewed, had over five years of experience in the pharma industry, worked in diverse roles in different stages of the pharma supply chain and all worked for multinational companies. I decided that six was a sufficient number of people to interview as it provided diversity of perspectives and allowed me to focus my resources on the quality of my interviews rather than the quantity.

Table 7 - Interview Participants

Interview	Company Headquarters	Job Title	No. Years in Pharma	Supply Chain Stage	Employment Country	Language	Interview Format	Interview Duration
Int A	1 - Japan	Operations Director	10 - 15	Primary Manufacturing	Ireland	English	Online	57 minutes
Int B	2 - Ireland	Procurement Director	10 - 15	Research and Development	Ireland	English	Online	54 minutes
Int C	3 - Ireland	Project Manager	5 - 10	Wholesale	Ireland	English	Online	39 minutes
Int D	4 - Spain	Operations Director	10 - 15	Distribution	Spain	Spanish	In Person	43 minutes
Int E	4 - Spain	Quality Director	5 - 10	Distribution	Spain	Spanish	In Person	27 minutes
Int F	5 - China	Quality Director	20 +	Secondary Manufacturing	Ireland	English	Online	27 minutes

Source: Own Elaboration

Before each interview, I messaged each participant to get their consent to do the interview, explaining to them what the focus of my research was, and the estimated duration of the interview. I also informed them that the interview would be recorded and that I would send them a consent form by email to be filled out before the interview. The consent form sent to the participants is available in Section 7.3 of the Annex and the confidentiality agreement that I signed before beginning the interview process is available in Section 7.4 of the Annex. I then arranged a time for the interview that would be suitable for the participant. For the participants that lived in Ireland, I sent the consent form and the ZOOM link. For the interviews that were in Spain, I went to the participants' office to do the interview and emailed the consent form to them the day before the interview.

During the interview, I tried to make my interviewees feel comfortable. I introduced myself if they did not already know me and told them the objectives of the interview. I thanked them for agreeing to do the interview and reassured them that the interview was confidential. I then asked them if I could record the interview and told them that there are no right or wrong answers and that I just wanted to know their opinion. I used active listening during the interview, repeated what they were saying back to them and asked follow up questions. For the interviews in Spanish, I asked the participants to speak slowly and clearly so I would be able to understand them better and so I would be able to easily transcribe the interview afterwards. After I finished my interview questions, I asked them if there was anything else they would like to add, thanked them again for their time and made small talk.

I conducted my first interview as a pilot interview. I conducted field-testing to ensure the clarity of the questions, the flow of the interview, and the quality of the responses. This interview was also used to judge the timing of the interview. The first interview script consisted of forty-seven questions which I was unable to finish in under an hour. I found that I had too many introductory and broad questions which did not allocate me enough time to go in-depth for the questions regarding reshoring. I also found that some questions were unclear which led the participant to misinterpret what I was asking. After the pilot interview, I reduced the quantity of questions to thirty-one questions to ensure that I would have the time to get good quality responses about reshoring. I also changed the phrasing of the questions that were ambiguous to make them clearer. This was done to ensure that the data I collected in the following five interviews would be of high quality. The updated interview script is available in Section 7.2 in the Annex.

I recorded the interviews using three mediums – Zoom, iPad, and by phone. This ensured that in the case of a technical failure, I would still have my interview results. After I completed the interviews, I began the data coding process. I transcribed each interview to facilitate the writing and analysis of the results. I used transcription tools provided by Google Docs to aid me in the transcription of the interviews. I then read over the interview transcripts to familiarise myself with the data collected. I created codes for each of the six interview themes – pharmaceutical supply chain, location decisions, trends in the industry, globalisation, Covid-19, and reshoring. These codes were linked to my research objectives, and therefore would facilitate the answering of these objectives in the discussion section of this paper. I applied the codes to the interview transcripts, and in the results section below, I discuss the results of the interviews under the six codes.

4. Results

In this section, I will present the results of the semi-structured interviews. I will compare and contrast the results from the six interview participants and include relevant quotations. The order of this section is outlined below:

Section 4.1 – Pharmaceutical Supply Chain
Section 4.2 – Location Decisions
Section 4.3 – Trends in the Industry
Section 4.4 – Globalisation
Section 4.5 – Covid-19
Section 4.6 – Reshoring

4.1 - Pharmaceutical Supply Chain

In presenting the participants my elaboration of a pharmaceutical supply chain, there was a general consensus that the supply chain was correct yet basic. Int C described the supply chain as a *"high level summary."* Int A suggested adding in legal and administrative flows into the diagram and include the transport method for the material flows. Int A also advised that there are often multiple suppliers for key starting materials and APIs. Both Int C and Int F stated that there are often more than one wholesaler and to include *"prewholesalers."* Int D also stated that there are frequently multiple distribution centres and suppliers and that there are often intermediary services between each flow. Int C and Int F suggested that I distinguish between the different types of providers such as pharmacies, hospitals, shops etc.

In terms of the different disruptions that can affect the pharma supply chain, the participants reported multiple different disruptions. Table 8 below outlines the different disruptions described by the participants. The disruption most frequently cited by the participants was Covid-19 with five of the six participants mentioning it. Adverse weather conditions, inflation, and war such as the war in Ukraine were both mentioned by three participants. Remarkably, Int A and Int F mentioned purchasing or shipping APIs from India and China as a source of disruption stating that *"you have more complicated supply chains with [India and China]"* causing delays such as products being unable to get through canals, products blocked due to invoice reasons in India and other documentation issues. In the table, drug shortages have been included as a disruption in the pharmaceutical supply chain. It is important to note however, that drug shortages are an effect of disruption and not a disruption in itself. However, it has been included in the table as two participants mentioned it.

The participants mentioned multiple strategies and tools to prevent or minimise the impact of disruptions. Int A, C and F recommended keeping extra stock to minimise the impact of disruptions. Int C stated that their company's strategy was to *"financially keep the stock as low as possible while also considering patient risk."* Int F spoke about keeping 12 months' worth of stock for critical products whereas Int C stated that their company held between 12 – 60 days of stock depending on the product. Additionally, Int A, C, D spoke about the use of forecasting tools to estimate demand which would allow companies to negotiate with suppliers the price and quantity of APIs they require. Furthermore, Int E and F spoke of having more than one API supplier to have *"reliability within your supply chain."*

Four of the six participants believed that disruptions are becoming more frequent and critical. Int D spoke that *"globalisation has made supply chains a lot more complicated."* Int A said that *"the world is becoming more volatile."* Only Int B and Int F disagreed with the question. Int B claimed that *"every year there's something different so you have to be as flexible as you possibly can to embrace the*

changes that are afoot and have a flexible business that can adapt to it." Int F disagreed as they believed that *"supply chains are more robust and have more flexibility."*

Table 8 - Disruptions in the Pharmaceutical Supply Chain

	INT A	INT B	INT C	INT D	INT E	INT F
Covid-19		x	x	x	x	x
Inflation	x			x	x	
Quality Issues	x					x
Regulation	x				x	x
India/China	x					X
War		x		x		x
Climate		x	x			x
Drug Shortages				x	x	
Strikes	x					

Source: Own elaboration based on interviews

There were multiple challenges mentioned by the participants in managing a pharmaceutical supply chain. Int B spoke of the increase in cyberattacks in the industry and the necessary improvements in data protection and information technology (IT) security. Int C and Int F reported that ensuring quality was a challenge in the industry with Int C stating that *"the quality requirements in Ireland and other countries has jumped in the past 10/15 years."* Int D spoke of the challenges of managing a global supply chain which include *"having a good control circuit, flow of documents and managing merchants between different business units and production centres."*

4.2 - Location Decisions

There are multiple considerations for companies to decide on the production location of their API as outlined in Table 9. The factor most mentioned by the participants was the cost of labour. Int F described cost as a fundamental factor as it has *"a knock-on effect on the price on your finished goods which has a knock-on effect on the price you can charge a patient which determines your profitability."* Int A agreed with this but believed it was a more important factor for generic brands which are produced at a high volume. For more niche APIs that are produced at a lower volume with a greater profit margin, Int A believed that proximity was a more important factor. Int A said, *"where you're not really worried about the overall cost of your billing materials for your API, you'll pay a bit more to have a local supplier in Germany or Spain."*

The proximity to the market in which a product is sold is a consideration for three of the participants. Int A stated that you are *"not going to produce in the U.S. if only licensed to sell in Europe."* Int C argued that proximity to the market signifies the product reaching the patient more quickly which *"reduces the patient risk."* However, both Int A and Int E consider the supplier more important than the geographical location. Int A stated that *"I think it's more to do with the capability of the site"* with Int E stating that *"the location itself is not usually a problem"* and only in the case of *"shortages, you should look for a closer producer."*

Table 9 - Factors that affect the Geographical Production Location of API

	INT A	INT B	INT C	INT D	INT E	INT F
Availability of Skilled Labour			x			
Cost of Labour	x		x	x		x
Cost of Logistics			x			
Cost of Real Estate			x			
Country Environmental Policies				x		
Country Reputation – Quality & Risk	x			x		x
Country Regulation	x			x		x
Country Taxes & Tariffs			x	x		
Criticality of Product						x
Proximity to Market	x		x			x
Supplier's Relationship with Company	x					
Supplier Performance	x					
Supplier Capabilities	x					
Supplier Location	x	x				

Source: Own elaboration based on interviews

Both the country's reputation in terms of quality and risk, and the country's regulation were also important factors, both mentioned by three participants. Many participants spoke about the differences in production in different continents. Int D stated that in Europe, there is more investment in research and development, the costs are higher due to higher taxes, regulation, and environmental policies and the quality is higher. Int A also disclosed that regulation is higher in the EU. Int D spoke of the lower labour costs, taxes, less strict environmental policies, and greater level of contamination in India, China, and other parts of Asia. Int A stated that there are *"more issues with Indian suppliers than with EU suppliers."* Int C spoke of the long delivery times associated with producing in China which can vary between 3 days and 6 weeks. Int C said that *"if you were in that country, you would have to hold at least 6 weeks stock for a product worth one thousand euro per unit. You are balancing your financials against patient risk."*

In contrast to Int D, Int E claimed that the quality of goods produced in Asia is the same as those produced in Europe. Int E stated that *"if a drug is sold in Europe, it can only be sold if it complies with European regulation."*

When asked where APIs are produced, four of the participants mentioned China and India as the primary producers. Int A called India *"the leader of API production."* Outside of Asia, the participants mentioned Germany, Italy, France, Spain, and Ireland most frequently.

4.3 - Trends in the Industry

The participants mentioned different trends that could affect the pharmaceutical industry. Int B and Int C spoke of the developments in AI that could affect the supply chain. Int B spoke of the use of AI in supply chain and sourcing. Int C spoke of other investments in technologies such as 3D modelling and automation to speed up the logistics of moving products in the pharmaceutical supply chain. Int A and Int E mentioned the improvements and innovation in biologics with both of them agreeing that the *"industry is moving towards biologics."* Int A claimed that there have been improvements in oncology, gene therapy and cell therapy and greater investments in blood plasma, special and rare diseases.

Int D spoke of the investments and greater pressure for the European production of APIs, the increase in production costs worldwide and the rising demand for pharmaceutical goods. Int D stated that there is great encouragement for India and China to improve their environmental regulation and standards. Due to the rising cost of production worldwide, *"companies are evaluating if it is still competitive to produce in Asia or if they should move to Europe."* Int D cited the rising middle class in India and other developing countries as a factor influencing the price increases.

Int C seconded the opinion that there is increased investment in Europe stating that *"across Europe, pharmaceutical jobs are up 13-15%."* They cited the supply chain issues created by Covid as the reason for this. Int F similarly spoke of the *"integration of supply chains"* as a trend in the industry.

4.4 - Globalisation

The participants were unanimous in stating that the pharmaceutical industry has been affected by globalisation. Int B stated that *"globalisation of the business is key to us."* The pharmaceutical industry has become a global market which Int F stated, *"has been driven by cost."* Int E said that globalisation has affected the industry *"positively"* and that *"you can buy in India and the quality is the same but at a much lower price."* Int D spoke of *"cost, taxes and regulation"* as drivers for companies to move production to other countries. Int F stated that the industry has gone *"from sourcing in Europe to sourcing outside of Europe, predominantly India and China."*

Int C spoke about how globalisation has created larger more global pharmaceutical companies with more acquisitions. Int C also spoke about the rise of *"specialist companies"* who are third-party companies that provide services to the big pharma companies such as production of a company's APIs or packaging of the finished product. This is cheaper than big pharma companies having their own *"warehouses or production centres."*

4.5 - Covid-19

Five of the six participants believed that Covid-19 had an effect on the pharmaceutical supply chain. Int A was the only participant who disagreed with the question stating that there was a *"bump"* when Covid-19 initially broke with difficulties getting *"Key Starting Materials out of China."* However, Int A felt that the thirteen to sixteen weeks of inventory they held for API and finished pack allowed their company to *"absorb those issues on a shorter term and get [production] back up after the restrictions lifted."*

Int D felt that Covid-19 had a large effect on logistics stating that it caused shipment delays through planes and boats not being able to leave ports, increases in transport costs and shortages of shipping containers. Int D stated that *"what would take ten days to ship before Covid, took thirty days during*

Covid." Int E mentioned the closure of borders, protectionism, price increases and increase in demand for anticoagulants and antipyretics which led to drug shortages. Int F also stated that there were drug shortages for vitamin D products and a cardiovascular product. They also disclosed that many companies declared force majeure on their contracts. Int C believed that Covid-19 added more people into the supply chain, increasing costs for companies.

Four of the participants spoke of the ways that companies have adapted since Covid-19. Int C spoke of companies finding ways to strategize to become leaner to counteract the cost increases associated with *"Inflation, Covid and [the war in] Ukraine."* Int D talked about an increased number of *"alliances with logistics companies."* Int E spoke of companies looking to diversify their supply chain and having a *"plan B."* Additionally, Int F spoke of companies *"building more stock internally to allow for the inevitable of something happening to the initial starting site/API site."*

4.6 - Reshoring

There were multiple solutions mentioned by the participants for strategies to strengthen supply chains. Five of the participants believed that location strategies such as diversification, nearshoring, and reshoring would be appropriate solutions to strengthen supply chains. Int C advised to *"diversify and manage the risk across multiple geographic locations with the right supply chain."* Int D similarly stated that companies should *"diversify and have production centres in countries like France/Italy/Germany to not just depend on a few countries."* They explained that *"outsourcing is a good strategy to reduce costs but it's not always the strategy that guarantees a good supply"* and that *"problems in one or two countries can paralyse the whole supply chain."* Int A agreed with this and stated that *"if you're only getting your API out of India and China then you may be at an increased risk of supply chain disruption"* and *"it's usually the API suppliers in the Asia Pacific markets that is holding us up due to a delivery issue, a boat issue, a tax issue or a disruption notice that is in the site."* Int E and Int F spoke of nearshoring strategies in Europe as ways to strengthen supply chains. Int B spoke of creating and implementing effective *"standard operating procedures that are adaptable to the country and the region"* and to have *"good partners that are able and willing to address inevitable issues."* Two other strategies mentioned by Int F was to *"build relationships with API suppliers"* and for *"India and China to improve their regulatory history as people don't have the same confidence in a company supplying from India as you would from a company supplying from France/Spain/Germany."*

Four of the six participants believed that pharmaceutical companies are considering reshoring with one participant unsure and Int F disagreeing saying that they are not considering reshoring *"to a huge extent due to cost implications."*

There were multiple drivers and barriers discussed by the participants for the implementation of reshoring. Table 10 outlines the different drivers for reshoring and Table 11 outlines the different barriers.

The main drivers for companies to implement reshoring is to reduce supply chain risk and to increase supply chain reliability. Every participant stated this as a driver for reshoring. Four participants believed that increased supply chain control is another driver with Int C declaring that *"The lesson learned from Covid and [the war in] Ukraine is that [API production] is too far away from a particular company to manage."* Int E stated that the ability to *"get in contact quickly"* and *"visit the factory yourself"* was a key advantage to this strategy as it increased the control over the supply chain. Int F stated that a *"shortage supply chain would be easier to manage."*

Table 10 - Drivers for Reshoring

	INT A	INT B	INT C	INT D	INT E	INT F
↑ Brand Image					x	
Currency						x
↑ Demand				x		
Proximity to Market			x		x	
↑ Costs in Asia				x		
↓ Delivery Times			x		x	
↑ Control			x	x	x	x
↓ Risk + Reliability	x	x	x	x	x	x
↓ Transport Costs				x		
↑ Quality				x		x

Source: Own elaboration based on interviews

Int D stated that *"countries like China are introducing stricter environmental and labour policies"* and that in the future *"it won't be as cost effective to produce there."* Int D also spoke of the driver of decreased transport costs due to reshoring as *"many companies have to send products two/three times which increases costs a lot – especially with inflation."* Int C and Int E spoke of shorter delivery times due to market proximity as a driver which decreases patient risk and improves efficiency. Int E discussed brand perception as a driver, as even though they do not believe the European API's quality would be superior, many consumers may think otherwise, potentially resulting in an improved brand image for the company.

Table 11 - Barriers for Reshoring

	INT A	INT B	INT C	INT D	INT E	INT F
↑ Cost			x	x	x	x
Licensing	x		x			
Previous FDI		x				
Regulation	x					
Shareholders						x
Skilled Labour						x
↑ Taxes					x	
↑ Time	x					
Trade Laws	x					
Unions	x					

Source: Own elaboration based on interviews

Four of the participants mentioned cost as a key barrier to reshoring. This includes both relocation costs and production costs after reshoring is implemented. Int C said that *"it's probably a difficult one to swallow if you're making a product for ten cents and now you come to Europe and you're making it for a euro."* Furthermore, Int F spoke of the difficulties in getting shareholders to agree to reshoring as their concern is their return on investment. Int B pointed out the large investments that a company has already made in their production sites in other countries and how this sunk cost would be a barrier for them to move.

Int A discussed the lengthy time frame to implement reshoring and the regulation that could create a barrier. Int A asserted that *"moving an API from country to country is not something that you want to do freely and certainly in the pharmaceutical industry it's not something you want to do regularly because it can create a lot of headache."* Int A spoke of the time it could take to get regulatory approval for location changes which can take *"3/4/5 years if the product is sold in Thailand or the Philippines."* This can create an issue for companies as they have to *"maintain supply in the markets that [the company] is supporting"* while waiting for this regulatory change and are left in a *"dual process managing both supplies."*

The participants spoke of ways to mitigate the barriers to reshoring. Int C proposed the use of *"lean management"* and technology such as AI to drive the *"costs down for labour and skilled labour."* Int F proposed nearshoring to Eastern Europe to reduce the costs of reshoring. Other participants spoke of public policies to mitigate the barriers. Int C suggested that governments should implement training and education for a workforce to be equipped for reshoring. They said that governments should have *"the workforce or putting the training in place in advance to say that we can supply you with 2000 skilled operators."* Int A suggested that *"governments could help with trade agreements and the flow of goods and services."* Int B, C, D and E recommended tax breaks or incentives to encourage reshoring. Int B affirmed that *"government policies at a macro level, drive those types of decisions."* Int F refuted the use of public policy to mitigate barriers for reshoring asserting that *"It would be very hard to do anything because it would go against the whole EU Single Market, free trade and different agreements we have with multiple countries worldwide."*

The participants did not unanimously agree on any one country that companies can reshore to. Int A believes that reshoring should be to *"countries that have the technology and the infrastructure to support what [the company] needs."* Int B thinks that it should be somewhere closer to the consumer, in a cost-effective region and that companies need to take world events into consideration. Int C suggested Ireland as *"the only English-speaking European country"* but did refer to the real estate in Ireland as an Issue. Int E and F spoke of Eastern European countries with Int E considering Poland as a good option as it has low production costs, low taxes, the capabilities to produce API and is strategically located.

The participants agreed that reshoring should be partial. Int D affirmed that reshoring should be partial to *"secure the supply chain while also taking advantage of low costs."* The participants recognised that only certain companies in the industry would implement reshoring and that these companies would most likely be big pharma companies. Int D recognised that *"not every company has the luxury of being able to maintain different production centres around the world"* and *"it has to be large companies that have the sales and financial structure to be able to reshore."* Int F agreed that *"It would be driven by bigger companies like Pfizer or Merck and then smaller companies would potentially follow but it would take a big player in the market to make that decision."* Int C said that it would be companies where *"market share is more of a driver than cost."*

The participants agreed that the APIs that would be reshored would be innovative APIs and not generics. Int D suggested *"oncology drugs, drugs for fatal diseases and complex APIs."* Int E proposed *"molecules that are more specialised and have complicated production processes, ones that are subject to shortages."* Int F affirmed that it would be innovative as companies *"can charge a premium."* The participants did not think that generic APIs would be reshored as they are competing in terms of costs. Furthermore, Int D declared that *"a lot of key starting materials come from China/India, so it doesn't make sense to produce generics in Europe."*

When asked if reshoring would make an impact on the various supply chain flows, the participants gave various responses. Int D believed that there would be a smaller quantity of financial transfers and reshoring would signify less negotiating with partners. Int F stated that from a financial perspective, it would be easier for companies as they would be trading in the same currency. Int E thought that it would increase innovation – driving companies to improve the molecules they are producing so patients will be willing to pay more for the better products.

To conclude the interview, Int E added that *"Reshoring is not fundamental, and globalisation is not going to be reversed."* They stated that *"For diversification, reshoring is principal, but you can do a lot more."* Int B similarly said that *"I would never say that companies repatriated back to their homeland is a good idea and I think it's fantastic for companies to be able to take advantage of different cultures and ways of working."*

In the discussion section, I will analyse and contrast the outcomes obtained in this section with the findings from my comprehensive literature review, drawing final conclusions and offering recommendations.

5. Discussion

In this section, I will compare and contrast the information gathered from my literature review and the results from my interviews. In doing this, I will be able to provide conclusions and recommendations that will answer my research questions. The order of the discussion is provided below:

Section 5.1 - Identify the different stages in the supply chain of a medicine
Section 5.2 - Identify the different disruptions and challenges in pharmaceutical supply chain management
Section 5.3 - Identify the factors that influence the location of the production of an API
Section 5.4 - Analyse the impact globalisation and Covid-19 had on the pharmaceutical supply chain
Section 5.5 - Identify ways in which companies can secure their supply chain of active pharmaceutical ingredients
Section 5.6 - Identify the drivers and barriers for reshoring and ways to mitigate barriers

## *5.1 - Identify the different stages in the supply chain of a medicine*

From the information I gathered in my literature review, I created an elaboration of a supply chain diagram (Figure 2) which I presented to my interview participants. The feedback that I was given was to include flows other than the material flow. The participants spoke to me about the intricacy of the pharmaceutical supply chain and the multiple suppliers that are involved in the supply chain which differ greatly by product and by company. Using this information, I have created an updated supply chain diagram that represents the complexity of the pharmaceutical supply chain. This can be seen below in Figure 5.

5.2 - Identify the different disruptions and challenges in pharmaceutical supply chain management

Drug shortages have been recognised globally as a key issue in the pharmaceutical industry for many years. Over recent years, drug shortages have increased dramatically with the European Commission stating that between 2000 and 2018, drug shortages in the EU had increased 20-fold (Colin-Oesterlé, 2020). There are multiple different disruptions and challenges that practitioners face in pharmaceutical supply chain management to prevent drug shortages. According to the semi-structured interviews, geopolitical events are the greatest source of disruption in the supply chain. Due to the globalised nature of the pharmaceutical industry, geopolitical events can have a significant impact on operations. MSSG (2023) stated that geopolitical events or trends such as Covid-19, the energy crisis, the war in Ukraine and high inflation rates can exacerbate drug shortages.

The interview participants most frequently identified Covid-19 as the greatest disruption in the pharmaceutical supply chain. The pandemic had profound implications, including shipping delays, price increases, an elevated demand for pharmaceutical products, protectionist measures, and border closures. These findings align with the literature review, which also highlighted Covid-19 as a disruption in the industry, leading to price increases, increases in pharmaceutical demand, and disruptions in the supply chain (Data Bridge Market Research, 2021). Collectively, these findings highlight the significant impact that Covid-19 had on the industry. In the same way, the war in Ukraine and inflation were also cited as disruptions in the pharmaceutical supply chain in both the literature review and in the interviews.

Figure 5 - The Pharmaceutical Supply Chain - (Version 2)
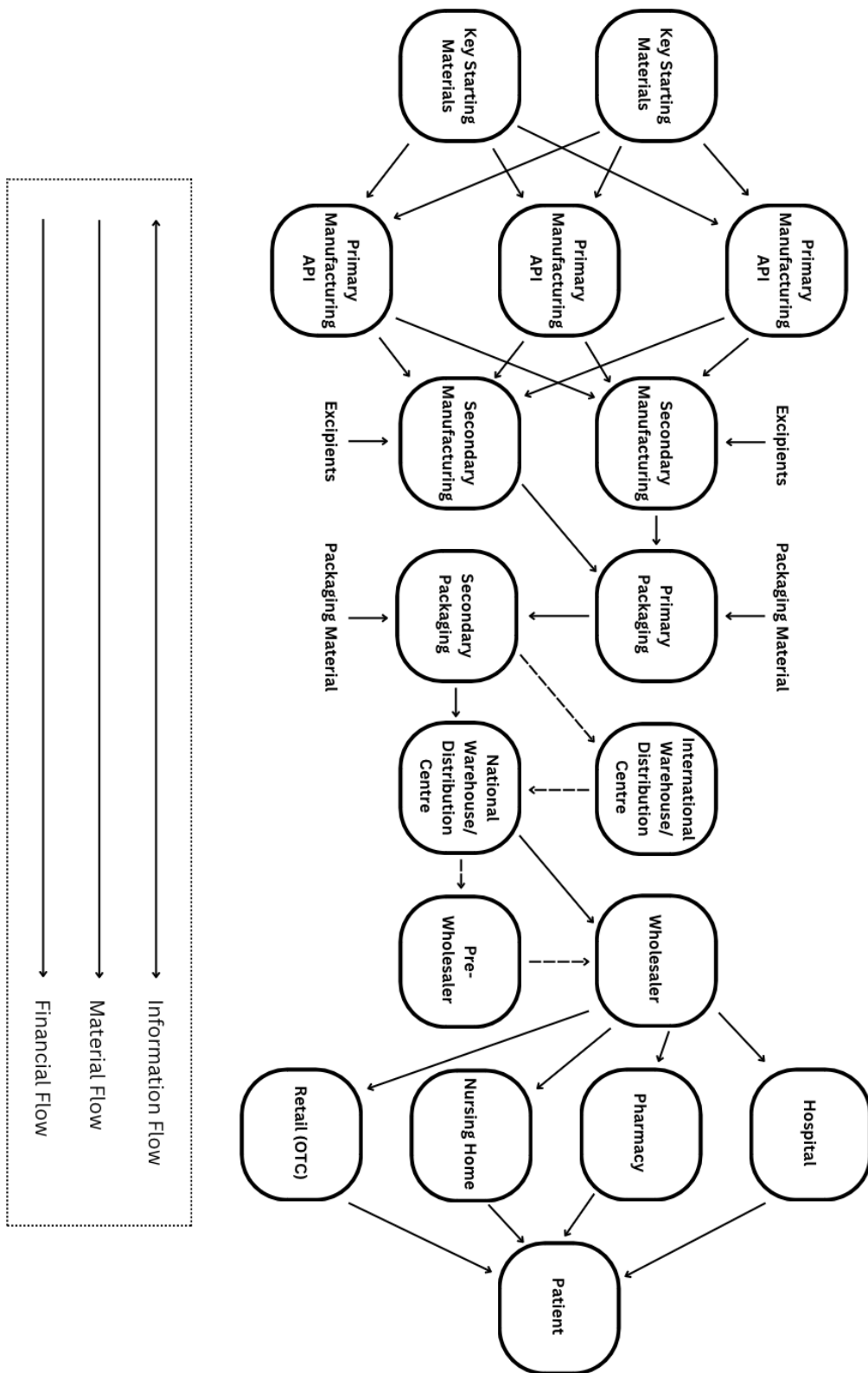
Source: Own elaboration based on results

The globalisation of the pharmaceutical industry can be a challenge to supply chain practitioners. The majority of APIs are manufactured in India and China, primarily driven by lower production costs. However, the concentration of production in these regions signifies that any disruption can have a ripple effect on the entire supply chain. This was evident at the beginning of the Covid-19 pandemic when China's implementation of lockdown measures had a significant impact on the pharmaceutical industry affecting APIs, raw materials, shipments, procurements, FDF drugs, and much more (Sharma et al., 2020). Moreover, many interview participants spoke of the increased number of disruptions associated with sourcing from these countries. This is discussed in further detail in Section 5.3 and 5.4.

Supply chain practitioners often encounter challenges in ensuring compliance to regulation which are essential to ensuring the quality, safety, and efficacy of drugs. Two of the interviewees spoke of the challenge of ensuring quality given the increasingly stringent quality requirements over the past decade. Another challenge that was identified in the interviews was the increasing number of cyberattacks in the industry. This has provoked companies to implement improvements in data protection and IT security. This finding was supported by Turner (2023) who highlighted the manufacturers' increased emphasis on cybersecurity.

Several of the unforeseen and inevitable geopolitical disruptions discussed earlier such as the Covid-19 pandemic and the war in Ukraine require the development of proactive and reactive strategies by supply chain practitioners. Establishing robust supply chains that are capable of adapting to shipping delays, drug shortages and fluctuations in demand becomes imperative to mitigate the impact of disruptions. In Section 5.5, I will provide a comprehensive analysis of potential strategies that practitioners can employ to enhance supply chain resilience.

5.3 - Identify the factors that influence the location of the production of an API

The factors that influence the geographical production location of API vary depending on the type of API. For generic APIs, the fundamental factor is cost and in particular the cost of labour. This was mentioned by multiple participants in the interviews with Int F describing that it has "a knock-on effect on the price of your finished goods which has a knock-on effect on the price you can charge a patient which determines your profitability." This has been corroborated in my literature review which describes how the majority of APIs are produced in China and India with the main factor explaining this being low production costs in these countries. As generic APIs mainly compete on cost due to the lack of patent protection and differentiation between products, companies are compelled to produce in locations which possess the lowest production costs which often are India and China. India and China have low production costs combined with the capacity to produce generic APIs in line with regulation in Europe which makes these countries extremely attractive to pharmaceutical companies that consider cost as the most influential factor.

The second most fundamental factor for the geographical production location of API is proximity to market. This factor is of more significance for innovative APIs that are produced in smaller volumes and have more complex production processes. As innovative APIs are often protected by patents, have little competition in the market, and often treat more critical illnesses, cost is not the most important factor for the geographical production location. The profit margin for innovative APIs is much higher than that of generic APIs which influences the production location. Int A stated that "where you're not really worried about the overall cost of your billing materials for your API, you'll pay a bit more to have a local supplier in Germany or Spain." The report by Pro Generika (2020) validates this as it stated that Europe focuses on the production of complex, smaller-volume APIs that have complex production processes and strict quality requirements.

Proximity to market signifies less supply chain risk to many of the participants in the interviews. This can be attributed to the belief that there are more supply chain disruptions and risks in producing and transporting APIs from India and China. According to the interview participants, these risks can include delays in delivery, regulatory issues, and contamination. For more profitable and critical APIs, companies focus more on the reduction of risks in the pharmaceutical supply chain which translates to a greater amount of production facilities in Europe.

Country reputation and regulation are factors that affect the production location of APIs. For companies and products where cost is the most significant factor, there is usually a lesser focus on country reputation. As mentioned above, China and India have a reputation for more supply chain disruptions and risks which can be a deterrent for companies in which there is a greater focus on supply chain resiliency. Country regulation can be interpreted in two ways – from one perspective low environmental regulation and quality standards translates to lower production costs for companies. On the contrary however, higher quality standards translate to better quality products which reduces contaminations and quality issues.

In the pharmaceutical industry, cost and proximity to market are the two most fundamental factors that companies must consider when deciding where to produce their APIs but as these factors are often in tension with each other, there is often a trade-off between them. Int E spoke of the need to "[balance] your financials against patient risk." In this way, companies need to find an equilibrium between low production costs and the risk of supply chain disruptions.

5.4 - Analyse the impact globalisation and Covid-19 had on the pharmaceutical supply chain

Globalisation has significantly affected the pharmaceutical supply chain. Over the past few decades, API manufacturing has moved from being domestically sourced to being outsourced from low-cost countries in Asia, predominantly India and China. This has been driven by low production costs, fewer environmental regulations, large-scale manufacturing and low barriers to entry for these countries (Bumpas & Betsch, 2009). These countries are especially attractive for the production of generic APIs who tend to compete on a cost basis. India and China are strong leaders in the production of APIs and have been growing their API manufacturing capabilities consistently over the past few decades.

Globalisation has led to a growth in the merchant market with an increasing number of specialised companies in all stages of the pharmaceutical supply chain. Large pharmaceutical companies presently tend to outsource different stages of the supply chain to third parties in order to reduce costs and/or dedicate resources to more profitable activities. This has created more complex pharmaceutical supply chains with an increased number of disruptions and vulnerabilities in the supply chain due to a wide range of key players and an over dependence of APIs in certain regions. Many interviewees mentioned that there are more disruptions associated with sourcing APIs from India and China than from European countries with an increased number of delivery delays, customs and regulatory issues, and contamination of products. Int D stated that "globalisation has made supply chains a lot more complicated" which has led to companies recognising the heightened importance of robust supply chains to ensure supply.

The Covid-19 pandemic exposed the dependency that the pharmaceutical industry has on the production of APIs in India and China. Covid-19 affected the pharmaceutical industry through price increases, increases in pharmaceutical demand and disruptions in the supply chain (Data Bridge Market Research, 2021). This was corroborated in the interviews with participants mentioning drug shortages, delays, increased costs, and increased demand for a variety of different drugs. In the post-pandemic era, companies are adapting and employing a variety of different strategies to strengthen

supply chains which include an increased number of alliances, building inventory levels, and diversification of the supply chain. Covid-19 also raised the attentiveness of global policymakers of the importance of a robust supply chain and has led to a number of policymakers worldwide to employ protectionist policies to strengthen the pharmaceutical supply chain in their state. Several companies have employed nearshoring and reshoring strategies as a means to diversify the supply chain. There has been increased awareness of these strategies as a solution for preventing disruptions in the supply chain by academics, companies, and policymakers. However, these strategies present inherent strengths and weaknesses and therefore may not be applicable to every pharmaceutical company.

5.5 - Identify ways in which companies can secure their supply chain of active pharmaceutical ingredients

There are a multitude of diverse ways in which companies can secure their supply chain of active pharmaceutical ingredients. The primary strategies mentioned in both my literature review and the interviews are inventory, supply chain management tools, alliances, and diversification.

Building inventory levels is a widely accepted strategy for cultivating robust supply chains. Turner (2023) identified this strategy as an area of concentration for companies. Many interviewees also spoke of this strategy to protect the supply chain from disruptions. The quantity of inventory recommended by the interviewees varied from twelve days to one year, indicating that it is a flexible approach tailored to the specific requirements of the company. According to Int C, the strategy requires a balance which is to "financially keep the stock as low as possible while also considering patient risk." In this way, companies must take into account their available resources and the criticality of the API that they are stockpiling.

The use of supply chain management tools is valuable in fostering resilience in the supply chain. The tools mentioned in the interviews included demand forecasting tools and modelling approaches, but there are a multitude of different tools to strengthen supply chain resilience. In my literature review, Sarkar *et al* (2022) discussed the use of modelling approaches such as mixed-integer programming, stochastic modelling techniques, simulation, and intertwined supply chain modelling. Turner (2023) spoke of Amgen's use of simulation modelling as well as supply chain risk monitoring, root-cause analysis, and performance tracking.

The formation of strategic partnerships with logistics companies and suppliers was another strategy identified in the interview process to reinforce a robust supply chain. The formation of partnerships with logistics companies helps to ensure the timeliness in the supply of products as well as optimising transport costs. Partnerships with suppliers can ensure a reliable and consistent supply of APIs facilitating regulatory compliance and cost optimisation.

The principal approach for guaranteeing supply chain resilience for the pharmaceutical industry revolves around the diversification of API sourcing. During the interviews, it became evident that this strategy was essential for ensuring a robust supply. Diversification can reduce the impact of disruptions as there is a decreased dependency on certain regions, it improves risk distribution, and promotes supply chain flexibility and adaptability in the event of a disruption affecting a supplier or geographic region. This strategy has also been proposed in my literature review with multiple academics stating its relevance. Paul *et al* (2021) suggested the diversification of sourcing markets with Turner (2023) mentioning how the pharmaceutical company Teva maintains at least two suppliers for each starting material and intermediate across two locations. Moreover, the European Commision (2020) mentioned the diversification of production and supply chains to achieve supply chain resilience. Elia *et al* (2021) stated that diversification allows companies to maintain their international network of

production and take advantage of national policies that governments have implemented to recover from the economic crisis caused by Covid-19.

Reshoring and nearshoring can be considered as diversification strategies when implemented partially. Partial reshoring can be regarded as a diversification strategy that involves retaining a portion of the supply in countries like India and China while simultaneously maintaining production in the domestic country. This allows companies to take advantage of the low costs associated with API production in China and India while also simultaneously reducing supply chain risk. This strategy is discussed further in Section 5.6.

Ultimately, my recommendation for companies would be to employ a variety of the different strategies mentioned above to strengthen pharmaceutical supply chains. Individually, these strategies may not be as effective in guaranteeing a robust supply chain than when implemented in conjunction with one another. The combination of strategies employed by each individual pharmaceutical company may vary depending on the company's resources, products, and specific requirements, but they all share a common goal of safeguarding supply continuity in a dynamic global market.

5.6 - Identify the drivers and barriers for reshoring and ways to mitigate barriers

Reshoring is the practice of returning or relocating a company's business practices to their country of origin (Morales Contreras & Leporati, 2020). It has been highlighted as a strategy that could build more secure supply chains for pharmaceutical companies that produce APIs. The main drivers for this strategy are increased flexibility, quality, and the importance of proximity to specific markets/end-users (Raza et al., 2021). In agreement with literature, many participants stated that increased quality, proximity to market, and control over the supply chain were drivers for this strategy. Proximity to market can signify reduced delivery times which is a benefit for an efficient supply chain.

The interviewees were unanimous in stating that the reduced supply chain risk and increased reliability were the main driver for reshoring. Baraldi *et al* (2022) identified similar benefits for reshoring, stating that the practice can decrease the number of drug shortages and therefore reduce the indirect costs of care, patient suffering, and antibiotic resistance. In terms of costs, reshoring allows companies to exploit economies of scale, avoid trade barriers, and tariffs when re-importing goods, and take advantage of nationalist and populist policies (Elia et al., 2021). One of the interviewees similarly mentioned the reduction in transport costs as a benefit for reshoring. Reshoring can also work as a form of improving brand image through the appearance of better-quality products and compliance with environmental regulation. This was reflected in literature as one paper stated that reshoring can better align supply chain strategies to corporate priorities and value propositions such as heritage and restored brand values or higher environmental sustainability (Robinson & Hsieh, 2016).

There are significant barriers that impede companies from implementing reshoring practices. The two most notable barriers are the high costs and the lengthy time frame required for companies to build new or upgrade existing API manufacturing facilities (Stark & Botos, 2021). In the interviews, it became apparent that cost was the largest barrier for the employment of this strategy. This includes both relocation costs and the production costs of APIs after reshoring is implemented. Similarly, the time frame required for reshoring is also a concern as companies require regulatory approval to move production. A barrier that was not mentioned in the interviews was the local availability of intermediates to manufacture APIs. If companies neglected to deal with this crucial point, it would move a country's dependence on foreign sources upstream in the supply chain, continuing the supply chain vulnerability (Sanchez & Muzzio, 2021).

Considering the barriers described above, my recommendation would be for companies who are interested in and capable of implementing reshoring to employ partial reshoring. Partial reshoring allows companies to take advantage of the low-cost production in India and China, while also diversifying, and reducing supply chain risk. Practitioners need to take into account their resources, product portfolio, company structure and competitive advantages when considering a reshoring strategy. Companies with a substantial global presence and greater resources are more likely to succeed in adopting reshoring strategies and effectively managing dual supply levels. Reshoring is a strategy that is likely more successful for core patented products. Reshoring that has been implemented in the industry has been implemented rarely and mainly for core patented products (Huq et al., 2016; Theyel et al., 2018). In the interviews, the participants were unanimous in stating that reshoring would not be a viable strategy for generic products. Generic products compete on price which simply would not be economically viable if the production were reshored to western countries. In this way, patented core products are likely to be more successfully reshored. Due to the high-profit margins and emphasis on innovation associated with these products, companies would be less impacted by the increased production costs incurred through reshoring.

Another possible strategy to make reshoring more economically viable is to nearshore to Eastern European Countries such as Poland, Hungary, and Slovenia. This was previously discussed by Javorcik (2020) who mentioned the option of reshoring to these countries due to their low labour costs and high percentage of pharma exports. Similarly, this was mentioned in the interviews with Int E considering Poland as a viable option due to its low production costs, taxes, strategic location, and API production capabilities. In the same way, another option to reduce the elevated labour costs associated with reshoring is investment in automation. This was mentioned by Elia *et al* (2021) as a solution that could substitute labour.

Public policy's influence on reshoring's feasibility and attractiveness became evident in both literature and interviews. Elia *et al* (2021) spoke of the large acceptance that government support will play a critical role in the fostering and boosting of manufacturing relocation strategies. Similarly, the CEO of Sequens stated that "without the support of states, such reshoring will not happen" (Abboud & Peel, 2020). Governments can encourage reshoring through taxes, subsidies, and investment in education. The interviews revealed that tax breaks, incentives, and subsidies could make reshoring more economically feasible. Furthermore, one interview participant spoke of investment in training and education to equip a state's workforce for reshoring. In literature, this statement was consistent with Gurvich & Hussain (2020) who recommended that universities should collaborate with pharmaceutical companies to redefine the academic curriculum to create a skilled workforce.

An alternative approach to reshoring could involve establishing an independent European-based company. This was Sanofi's strategy who created a standalone company called EuroAPI that would combine the company's API commercial and development activities with six of its European API production sites (Sanofi, 2020). This would be an alternative solution to dealing with the sunk costs associated with previous investments in production sites abroad which was mentioned as a barrier by an interviewee.

Ultimately, the pharmaceutical supply chain is too complex for just one unique solution as stated by Raza *et al* (2021) and Baraldi *et al* (2022). Although reshoring may be a viable option for some companies, it may not be feasible for others as it does require a significant investment in time and resources. It is not an all-encompassing strategy, and its practicality depends on each company's resources, products, and specific requirements.

6. Conclusion

In this section, I will give a brief overview of the research approach employed to accomplish the defined research objectives. Subsequently, I will present a concise summary of the key findings of this paper as well as its limitations and the importance of this research for academia and supply chain practitioners.

This paper was an exploratory study that evaluated the potential of reshoring APIs to strengthen pharmaceutical supply chain resilience. The Covid-19 pandemic highlighted the dependency that the pharmaceutical industry has on the production of APIs in India and China. This has sparked discussion by academics, policymakers, and pharmaceutical companies on strategies to decrease this dependency and enhance the resilience of the pharmaceutical supply chain. One of the prominent strategies that emerged from this discourse was reshoring – the practice of returning or relocating a company's business practices to their country of origin (Morales Contreras & Leporati, 2020). This paper aimed to evaluate the potential of reshoring APIs to strengthen pharmaceutical supply chain resilience – identifying the drivers, barriers, ways to mitigate the barriers, and other relevant strategies.

The research objectives for this study were the following:

1. *Identify the different stages in the supply chain of a medicine.*
2. *Identify the different disruptions and challenges in pharmaceutical supply chain management.*
3. *Identify the factors that influence the location of the production of an API.*
4. *Analyse the impact globalisation and Covid-19 had on the pharmaceutical supply chain.*
5. *Identify ways in which companies can secure their supply chain of active pharmaceutical ingredients.*
6. *Identify the drivers and barriers for reshoring and ways to mitigate barriers.*

In order to meet my research objectives, I conducted both primary and secondary research. I began with secondary research which consisted of a comprehensive literature review that provided an overview on the current research on the topic. I researched topics such as supply chain management in the pharmaceutical industry, the effects of globalisation on the industry, disruptions and risks in the supply chain, and the redefinition of global supply chains including various strategies such as reshoring and nearshoring. Following the literature review, I conducted primary research in the form of semi-structured interviews. I used the findings from my literature review to develop an interview guide. The literature review helped me understand the gaps in my research that needed to be filled and complemented with the semi-structured interviews. I interviewed six professionals from the pharmaceutical industry. The interview participants worked in a range of different roles and stages in the pharmaceutical supply chain which allowed me to get a diverse range of responses and perspectives. In the discussion section, I analysed and compared the results from the interviews and the literature review to draw final conclusions and recommendations.

6.1 - Results

This paper found that reshoring is not essential to supply chain resilience and that there is no singular solution that can adequately address the complexity of the pharmaceutical supply chain. Reshoring is most likely to be successful when it is partial as this allows companies to take advantage of the low-cost production in India and China, while also diversifying, and reducing supply chain risk. Practitioners need to take into account their resources, product portfolio, company structure, and competitive advantages when considering a reshoring strategy. Companies with a substantial global presence and greater resources are more likely to succeed in adopting reshoring strategies and effectively managing

dual suppliers. Reshoring is more viable for core patented products due to the elevated production costs associated with reshoring.

The main drivers for reshoring include a reduced supply chain risk and increased reliability. The main barrier to reshoring is the high relocation and production costs associated with the strategy. Mitigation approaches for this barrier include nearshoring to Eastern European countries, automation, and public policy.

Besides reshoring, there are a multitude of different strategies that can aid companies in securing their supply chain of active pharmaceutical ingredients. These strategies can include inventory, supply chain management tools, alliances, and diversification. Companies should employ a variety of these strategies to strengthen their supply chains as in conjunction with one another, these strategies are likely to be significantly more effective.

6.2 - Limitations

While this paper provides valuable insights, it is crucial to recognise its limitations. This section outlines the potential constraints, shortcomings, and boundaries that should be taken into consideration when evaluating the validity of the findings.

This paper is an exploratory study that involved the interview of six professionals in the pharmaceutical industry. The limited number of interviews may affect the representativeness of the results obtained. If there were a greater number of interviewees, the study would have achieved a higher level of accuracy and comprehensiveness, leading to a more representative portrayal of the subject matter. Due to a lack of time and resources, this was not feasible for this study.

Another potential limitation for this research was the potential bias in the participant selection. Interview participants were found through connections which may affect the validity of the results as it was not simple random sampling. The participants also only worked in Ireland or Spain so the results may not be representative globally.

As I interviewed individuals who worked in diverse roles and stages within the supply chain, there was a wide range of perspectives and opinions. While this provided valuable insights, it created difficulties in drawing generalised conclusions. For the results to be more representative and valid, it would be of use to interview multiple people in the same role and the same stage of the pharmaceutical supply chain to be able to draw more generalised conclusions.

In conclusion, for the findings of this study to be of greater accuracy, it would be highly advantageous to interview a broader sample from multiple different countries, as well as creating more representation for people in distinct roles and stages in the pharmaceutical supply chain.

6.3 - Importance of the Research

This research paper is both relevant and valuable to academics studying supply chain management and practitioners in the pharmaceutical industry. This section outlines the value of this research paper to these two distinct groups.

Academically, this research paper fills a gap in the existing literature by examining the specific context of reshoring APIs in the pharmaceutical supply chain. It provides a comprehensive analysis of the potential drivers, barriers, strategies to mitigate these barriers, and other tactics to reinforce supply

chain resilience. This contributes to the academic understanding of supply chain management, reshoring, and its impact on the pharmaceutical industry.

This research paper is also of importance to practitioners in the pharmaceutical industry as it provides valuable insights into the potential advantages and risks associated with reshoring APIs. This paper provides key considerations in the reshoring of APIs as well as alternative approaches to strengthening pharmaceutical supply chains. This paper aids practitioners in making informed decisions when evaluating the feasibility and implications of reshoring APIs.

This research is unique as it combines academic research with the insights of professionals in the pharmaceutical industry. Through the combination of the two perspectives, this paper bridges the gap between theory and practice, providing the real-world experiences and practical considerations for the reshoring of APIs. This provides a more holistic evaluation of the potential of reshoring APIs in reinforcing supply chain resilience. This dual perspective strengthens the validity of the findings, making this paper highly valuable to both academia and supply chain practitioners.

7. Annex

Introduction

Ensure that they have the consent form signed - Ask for their consent to record the interview

Thank you for taking the time to participate in an interview that will help my research in discovering how location decisions regarding the production of active pharmaceutical ingredients affect the supply chain management of a pharmaceutical product. My objectives are to identify ways in which companies can secure their supply chain of active pharmaceutical ingredients, to identify drivers and barriers for reshoring and ways to mitigate these barriers. In doing my literature review I learned information that I would like to get your opinion of.

1. Can you tell me about your professional experience in the pharmaceutical industry?

Pharmaceutical Supply Chain Management

2. Here is a diagram of the supply chain of a medicine – do you think it is accurate? Is there anything else that can be added?

Figure 6 - The Pharmaceutical Supply Chain - Colour Version

3. Can you give me some examples of recent disruptions in pharma supply chains? Are they more frequent than in the past? More critical? Higher impact?
4. How would you define resilience with your own words? How important is supply chain resilience in the industry?
5. Can you describe specific challenges which companies face in the supply chain of APIs?
6. How do companies in the pharmaceutical industry work to ensure a reliable supply of active pharmaceutical ingredients?
7. How do companies in the pharmaceutical industry ensure that their active pharmaceutical ingredients are compliant with regulatory requirements in different regions of the world?
8. How do pharmaceutical companies manage the complexity of their global supply chains for active pharmaceutical ingredients, and what tools or strategies do they use?
9. Can you describe any best practices that pharmaceutical companies follow when managing their supply chain for active pharmaceutical ingredients?

Location Decisions

10. How do companies choose the production location of APIs?
11. What are the main drivers for the production location of APIs?
12. What are the main barriers for the production location of APIs?

13. Can you describe in which countries are APIs being produced? What type of APIs are these? Generic or innovative?
14. Do you think there is a difference in the production location of generic and innovative APIs?
15. How do companies in the pharmaceutical industry assess and manage risks associated with the location of their active pharmaceutical ingredient production?
16. Can you think of any companies that have experienced challenges in their supply chain due to the location of API production?

Trends

17. Can you discuss any future developments or innovations in the supply chain of active pharmaceutical ingredients, and how these might impact the pharmaceutical industry?
18. Can you think of emerging trends in the industry?
19. Can you think of technologies that could affect the industry?

Globalisation

20. Can you explain how the supply chain for active pharmaceutical ingredients has evolved over the past decade, and what factors have driven these changes?
21. Has globalisation affected the supply chain of APIs? In what way? In what countries?
22. What factors were drivers for globalisation?
23. If says price, ask if price is still the main driver?
24. Can you think of drawbacks of globalisation?
25. Can you discuss any challenges that pharmaceutical companies face when sourcing active pharmaceutical ingredients from emerging markets, and how these challenges can be addressed?
26. How do companies in the pharmaceutical industry ensure that their active pharmaceutical ingredients are of consistent quality, regardless of where they are produced?

Covid-19

27. Has Covid-19 affected the supply chain of pharmaceutical products?
28. Has Covid-19 affected APIs? In what way?
29. Can you give examples of companies affected by Covid? And products?
30. How have companies adapted since Covid?

The Covid-19 pandemic has opened up much discussion about the vulnerability that the pharmaceutical industry has on the production of APIs in India and China.

Reshoring

31. Can you think of strategies to strengthen API supply chains?
32. Have you heard of reshoring? Can you explain what it is?

Reshoring is the practice of transferring a business operation that was moved overseas back to the country from which it was originally relocated.

33. Do you think that pharmaceutical companies are considering reshoring? And nearshoring?
34. Can you think of any pharmaceutical companies who have reshored the production of APIs?
35. What are the main drivers for reshoring of APIs?

36. What are the main barriers for the reshoring of APIs?
37. What are ways to mitigate these barriers?
38. Where are companies considering reshoring to? What countries and why?
39. Do you think they will move to other Asian countries or European countries?
40. What are the benefits and drawbacks of reshoring APIs?
41. Do you think reshoring is an effective strategy to strengthen supply chains? If not, why? How else could they strengthen supply chains?
42. Do you think reshoring would be partial or full? What APIs would most likely be reshored?
43. How could reshoring affect information, material, intangible, and financial flows?
44. As India and China are experts in the production of APIs, do you think reshoring the production will affect the know-how?
45. Do you think that public policy could drive or create a barrier for reshoring?
46. Can you think of any government initiatives worldwide that could affect reshoring? Do you think these are effective strategies?
47. What other strategies can you think of?

Conclusion

48. Thank you for all your valuable information, is there anything else you would like to add before we end the interview?

Introduction

Ensure that they have the consent form signed - Ask for their consent to record the interview

Thank you for taking the time to participate in an interview that will help my research in discovering how location decisions regarding the production of active pharmaceutical ingredients affect the supply chain management of a pharmaceutical product. My objectives are to identify ways in which companies can secure their supply chain of active pharmaceutical ingredients, to identify drivers and barriers for reshoring and ways to mitigate these barriers. n doing my literature review I learned information that I would like to get your opinion of.

Pharmaceutical Supply Chain Management

1. Here is a sample supply chain architecture – do you think it is accurate? Is there anything else that can be added? Different flows?

Figure 6 – The Pharmaceutical Supply Chain – Colour Version
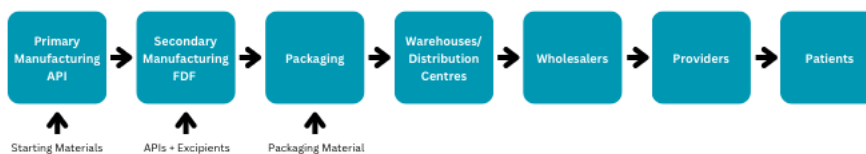
2. Can you give me some examples of recent disruptions in pharma supply chains? Are they more frequent than in the past? More critical? Higher impact?
3. Can you describe specific challenges which companies face in the supply chain of APIs?
4. How do companies in the pharmaceutical industry work to ensure a reliable supply of active pharmaceutical ingredients? Tools? Strategies?

Location Decisions

5. How do companies choose the geographical production location of APIs? Main drivers + Barriers?
6. Can you describe in which countries are APIs being produced? How does the country in which the API is being produced affect the supply chain?

Trends

7. Can you discuss any future developments or innovations in the supply chain of active pharmaceutical ingredients, and how these might impact the pharmaceutical industry? Emerging Trends/ Technologies?

Globalisation

8. Can you explain how the supply chain for active pharmaceutical ingredients has evolved over the past decade, and what factors have driven these changes?
9. Has globalisation affected the supply chain of APIs? In what way? In what countries?

Covid-19

10. Has Covid-19 affected the supply chain of pharmaceutical products? How? Examples of companies/products?
11. Have pharmaceutical companies adapted in any way since covid in terms of supply chains?

The Covid-19 pandemic has opened up much discussion about the vulnerability that the pharmaceutical industry has on the production of APIs in India and China.

Reshoring

12. Can you think of strategies to strengthen API supply chains?
13. Have you heard of reshoring and nearshoring? Can you explain what they are?

Reshoring is the practice of transferring a business operation that was moved overseas back to the country from which it was originally relocated. Nearshoring is transferring a business operation to a country closer to the country that it was originally located.

14. Do you think reshoring is an effective strategy to strengthen supply chains? If not, why?
15. What are the main drivers for reshoring of APIs?
16. What are the main barriers for reshoring/nearshoring? What are ways to mitigate these barriers?
17. What are the benefits and drawbacks of reshoring APIs?
18. Do you think that pharmaceutical companies are considering reshoring? And nearshoring?
19. Where are companies considering reshoring/nearshoring to? What countries and why? E.g., Spain with Morocco, England with Ireland
20. Do you think they will move to other Asian countries or European countries?
21. Do you think that the whole industry will implement reshoring policies or just certain companies? Why would some companies reshore and others not?
22. Do you think reshoring would be partial or full? What APIs would most likely be reshored?
23. It is mostly generic APIs that are produced in Asia, does it make sense to reshore generic APIs? Why or why not?
24. Can you think of any examples of pharmaceutical companies who have reshored the production of APIs?
25. How could reshoring affect information, material, intangible, and financial flows?
26. As India and China are experts in the production of APIs, do you think reshoring the production will affect the know-how?
27. How could reshoring be encouraged in the industry?
28. Do you think that public policy could drive or create a barrier for reshoring? How?
29. Can you think of any government initiatives worldwide that could affect reshoring? Do you think these are effective strategies? What other strategies can you think of for governments to help drive reshoring?
30. Do you think that there are any better solutions to reshoring?

Conclusion

31. Thank you for all your valuable information, is there anything else you would like to add before we end the interview?

Consent Form

For the purposes provided in Regulation (EU) 2016/679 and Organic Law 3/2018, of December 5, on Personal Data Protection and Digital Rights Guarantee, and due to the research project carried out by Ms. Alanah Gargan, a student at Universidad Pontificia Comillas, in which you participate, through this document you consent to the processing of personal data that you provide us within the framework of the aforementioned project by Universidad Pontificia Comillas, for the purpose of carrying out a thesis that will be submitted for evaluation to the Universidad Pontificia Comillas and/or published in an academic journal.

The aforementioned project/bachelor's thesis will contribute to identifying how location decisions in relation to the production of active pharmaceutical ingredients affects the global supply chain management of a pharmaceutical product.

Likewise, you are informed that:

- In no way will your personal data be mentioned in the results or publications derived from the research. In any case, and in accordance with current legislation, your anonymity will be guaranteed, adopting the necessary technical and organizational measures to ensure that it is not possible to know your identity.

- Participation in the aforementioned project is voluntary and its acceptance implies consent to the processing of your data by the responsible party for the described purpose.

- At any time, you may withdraw your consent and decline your participation in the project, without affecting the legitimate processing carried out to date.

- The data controller is Universidad Pontificia Comillas, with tax ID number R2800395B, with the address for notifications at Calle Alberto Aguilera, 23, 28015 Madrid.

- Contact Data Protection Officer: dpo@comillas.edu

- The legal basis for the processing is your consent under the terms established in Regulation (EU) 2016/679.

- In compliance with Regulation (EU) 2016/679 and Organic Law 3/2018, you are informed that you have the right to access, rectify, delete, limit processing, object to processing, and exercise your right to data portability, all free of charge, by writing to Universidad Pontificia Comillas – Secretaría General, Calle Alberto Aguilera, 23, 28015 Madrid, or to prodatos@comillas.edu. In

order to process your request, it is essential that you provide us with proof of your identity by sending a copy of your ID card, NIE, passport, or equivalent document.

- If you believe that your request has not been answered or that applicable data protection regulations have been violated, you may file a complaint with the Spanish Data Protection Agency (www.aepd.es).

- The data will be kept for as long as necessary to fulfill the purpose for which they were collected and, subsequently, for the period of prescription of any legal responsibilities of any kind. Once the legal prescription periods have elapsed, the data will be destroyed.

- You may consult our privacy policy at www.comillas.edu/ProteccionDeDatos

The undersigned declares to have read the content of this document and provides their free, informed, and unequivocal CONSENT for the processing of their data, according to the specific purposes and conditions set forth herein.

Name and Surname:

Date and Signature:

7.4 – Confidentiality Agreement

Ms. Alanah Gargan, student at the Universidad Pontificia Comillas is undertaking a bachelor's thesis on Global Supply Chain Management as part of a degree in International Business Administration and Management. (Hereafter referred to as the project)

Declaration

1. I acknowledge that individuals who participate in the project, and whose personal data I may have access to as a result, are entitled to the protection of their personality, human dignity, and privacy. I understand the importance of maintaining the confidentiality of any information related to their participation in the project.

2. I will ensure participant confidentiality throughout the process of preparation, presentation, review, authorization, publication, and dissemination of the project.

3. I acknowledge that participants have the right to have the confidentiality of their health data respected, and that no one may access such data without prior authorization.

4. In accordance with Article 5.1.f) of Regulation (EU) 2016/679 and Article 5 of Organic Law 3/2018 on the Protection of Personal Data and guarantee of digital rights, I recognize that I have a duty to maintain secrecy with respect to any information to which I have access during the course of the Project. I commit to exercising maximum care and confidentiality in the handling and custody of any information/documentation during and after the Project is completed.

5. I recognize that it is not appropriate to transfer, duplicate, or reproduce all or part of the information to which I have access in connection with the Project. I may not use the data provided by the participants for purposes other than the Project, or for any other purposes for which I was not authorized by the University's Ethics Research Committee.

6. I understand that I am personally responsible for complying with the duty of confidentiality, and that failure to do so may have criminal, disciplinary, or even civil consequences.

7. I commit to obtaining explicit consent from participants to record any sessions that may be necessary for the Project, informing them in the terms provided for in Article 13 of Regulation (EU) 2016/679. I promise not to use the recording for any other purpose and not to make copies of the recordings for external use.

8. With regard to personal information to which I have access, as well as any recordings made, once the necessary information has been extracted and incorporated into the data collection notebook, I will code or anonymize it appropriately to avoid the identification of the personal data subjects involved in the Project.

9. Any recordings made will be destroyed within five years from the date of recording.

10. I commit to respecting the ideals of COMILLAS,[1] and the Code of Conduct of the Society of Jesus in Spain.[2]

Therefore, I commit to ensuring that my conduct during the project adheres to the provisions outlined in the previous sections of this declaration, which I sign in duplicate.

In Madrid, 16th of March 2023

Signed: Alanah Gargan

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[1] http://web.upcomillas.es/presentacion/documentos/Cod_Conducta_Compa_Jes_Espa.pdf
[2] http://web.upcomillas.es/presentacion/documentos/Cod_Conducta_Compa_Jes_Espa.pdf

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