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Curriculum Business Organization and Strategy

The Italian Pharmaceutical Industry.

An analysis of the territorial distribution across the country.

L'industria farmaceutica italiana.

Un'analisi della sua distribuzione territoriale attraverso il Paese.

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ABSTRACT

L'elaborato è stato sviluppato con lo scopo di analizzare i determinanti della distribuzione dell'industria farmaceutica e biotecnologica nel territorio italiano.

Per raggiungere l'obiettivo della tesi viene fornita inizialmente una panoramica sull'industria farmaceutica globale e su quella europea, descrivendone alcuni fenomeni particolari come quello del Parallel Trade. La prima parte dell'elaborato presenta inoltre un'analisi approfondita dell'industria farmaceutica italiana, facendo riferimento anche ad una delle sue componenti rilevanti, ossia l'industria delle biotecnologie.

La seconda parte dell'elaborato, quella empirica, è stata introdotta dalla letteratura, scritta negli anni in merito alla complessità dei prodotti farmaceutici e al loro vantaggio comparato. In seguito, sono stati raccolti ed elaborati dati provenienti da database sulle regioni italiane in un arco temporale di 10 anni. Interpretandoli, è stato possibile concludere che un buon livello di istruzione terziaria della popolazione è una delle basi della concentrazione di lavoratori nell'industria farmaceutica in determinate zone. Concetto valido in maniera minore per l'efficacia governativa regionale e addirittura ancora meno per la corruzione, in quanto, all'aumentare di quest'ultima, diminuirebbe in modo significativo la presenza di personale impiegato nel settore farmaceutico.

Questi risultati confermerebbero la teoria promossa dall'economista Costinot, secondo cui la combinazione di capitale umano e di un determinato livello di qualità istituzionale favorirebbe la specializzazione e la localizzazione di un determinato settore in una determinata area.

INTRODUCTION

The activity of pharmaceutical companies is aimed at meeting the fundamental health needs of citizens through the production of the drug. Drugs companies are responsible of medicines development, production and selling. Science and technologies cooperate in this sector, which has the highest R&D expenditure.

The following work of thesis is developed in order analyse the distribution of the Italian pharmaceutical industry across the country.

The elaborate is structured in such a manner as to provide, in the first part, an overview of the global and European pharmaceutical industries, focusing on the Parallel Trade phenomenon as a common practice in the drugs market. Moreover, this part, in particular the second chapter, will enter deeply in the Italian pharmaceutical industry, looking at its characteristics and data and concentrating on the presence and importance of multinational companies in the country. Finally, there will be an overview dedicated to the biotech industry, an important partner for pharmaceutical businesses.

The following second part will be introduced by a theoretical framework referring to some literal works, written over the years on the complexity of pharmaceutical products, on their comparative advantage and on some of its sources, important for the determination of the location of this industry.

As a result, the fourth chapter will analyse the pharmaceutical industry's distribution across Italy. After an introduction on the data collected on Italian regions, the empirical model will be presented and, subsequently, the results obtained with Gretl, then discussed to demonstrate what was stated in the literature and to explain the aim of this work of thesis.

CHAPTER 1. THE PHARMACEUTICAL INDUSTRY

This part of the thesis will show how the pharmaceutical industry is spread all over the world, taking into account its increasing importance for human health and for its research and development activities.

1.1. DEFINITION AND BRIEF HISTORY

The pharmaceutical industry has become a large and complex system that can be defined as a set of activities that aims at the research, discovery, production and distribution of pharmaceuticals. Those comprehend all the substances, drugs and medications used for the diagnosis, treatment and prevention of health diseases.

The history of the pharmaceutical industry can be placed in the Middle Age but it had a great take-off in the 20th century when most of the world's largest pharmaceutical companies were located in North America, Europe and Japan. Nowadays, due to the introduction of new technologies and the fact that it is driven by big profits and competition, the industry is changing and evolving continuously and many companies are striving to be the first to find some special cures for specific diseases.

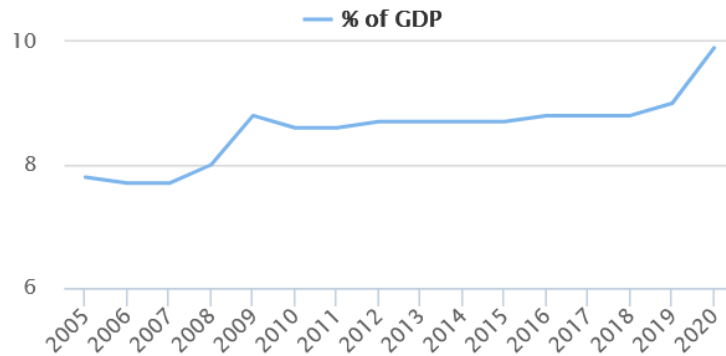
According to Statista¹, in the past two decades, this sector has grown significantly, above all in the last period due to the Covid-19 pandemic. The current scenario is dominated by multinational companies, many of them are from United States, that have the largest pharmaceutical market worldwide.

1.2. GLOBAL PHARMACEUTICAL MARKET

Starting from the data supplied by the Organization for Economic Co-operation and Development (OECD), the Health Spending as a Share of the GDP experienced a decrease in the early years of the 21st century due to the financial and economic crisis that started in the United States in 2006 and then spread, having a big impact on every industries and sectors all over the world. From that moment, as it can be seen in the Graph 1, there was an increase in the health expenditure and the impact on the GDP remains constant, until 2019 when the Covid-19 pandemic raise the importance of the healthcare system.

¹ Statista is a German leading provider of market and consumer data and statistics.

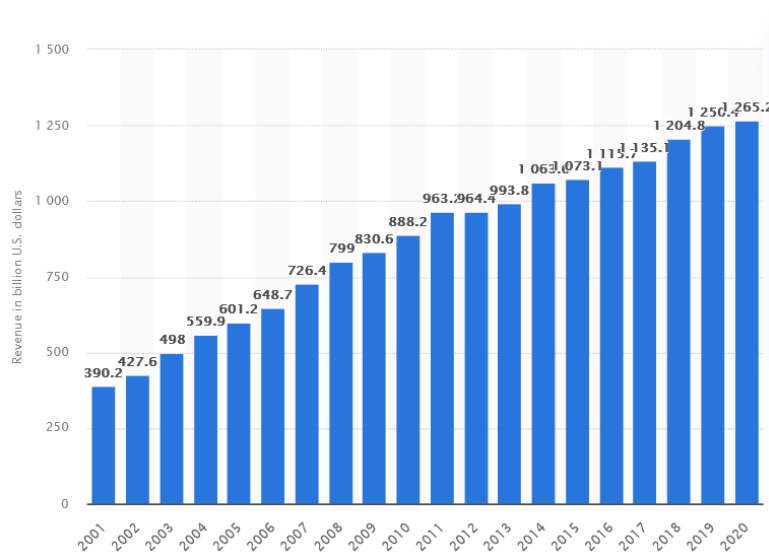
Graph 1. OECD Health spending as share of GDP, 2005 to 2020 (estimate).



Source. OECD Health Statistics (2021).

According to the following Graph 2 supplied by Statista, the pharmaceutical market reported an exponential increase in its revenue from 390 billion U.S. dollars in 2001 to 1.27 trillion U.S. dollars in 2020. This is partially due to the Covid-19 but most of this rise depends on how people get medicines and what they pay for them. The majority of sales covers the need of treatment for chronic conditions, like cancers, diabetes or autoimmune diseases.

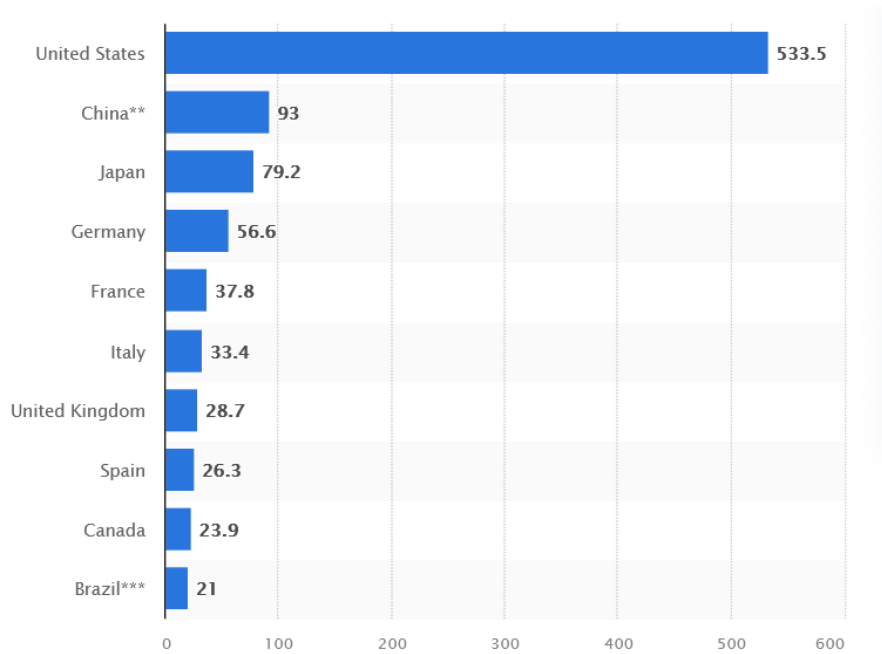
Graph 2. Revenue of worldwide pharmaceutical market from 2001 to 2020 (in billion U.S. dollars).



Source. Statista (2021).

In this scenario, United States seem to be a leader, having the biggest pharmaceutical market worldwide with the highest total revenues, while Italy ranks only sixth.

Graph 3. Revenues of top 10 national pharmaceutical markets worldwide in 2020 (in billion U.S. dollars)².



Source. Statista (2021).

In Graph 3, prices are reported at the ex-manufacturer level, that are prices when sold from manufacturer to wholesaler or direct to pharmacies.

Referring to the previous graph and looking at the pharmaceutical companies ranked on their revenues in billions of Dollars in the year 2020, most of them are based in USA and are the following:

² The notes indicate that China data regard health system, in particular hospitals data, while Brazil regard pharmaceutical market only.

- Johnson & Johnson (82.58) – **New Jersey**.
- Sinopharm (69.50) – China.
- Roche (64.60) – Switzerland.
- Bayer (49.99) – Germany.
- Novartis (48.66) – Switzerland.
- Merck & Co (47.99) – **New Jersey**.
- GlaxoSmithKline - GSK (46.52) – United Kingdom.
- AbbVie (45.78) – **Illinois**.
- Sanofi (43.21) – France.
- Bristol Myers Squibb (42.52) – **New York**.
- Pfizer (42) – **New York**³ .

They are the so-called “**Big Pharma**”: a term, sometimes used in a critical sense, that defines the international pharmaceutical companies. Their business model is characterized by the ability to identify new medical technologies, test in large experimental institutes and promote the results with intense marketing and sale work.

³ SISMED (2021), *Cosa sono le Big Pharma e perché tutti ne parlano?*, <https://www.sismed-it.com/big-pharma-cosa-sono/> [12.10.2021].

1.3. EUROPEAN PHARMACEUTICAL INDUSTRY

The European Federation of Pharmaceutical Industries and Associations (EFPIA) states that “*thanks to the advances in science and technology, the research-based pharmaceutical industry is entering an exciting new era in medicines development*”. In fact, this revolution is driven and drives the medical progress that aims at finding innovative treatments and make them available and accessible to patients. Some of these improvements make it possible the reduction of mortality and the increase of patient well-being: for instance, the total number of deaths among AIDS cases in Europe decrease from 2587 deaths in 2010 to 774 in 2019⁴.

The pharmaceutical industry is also considered a key asset of the European economy, with its high-technology sectors that allow to develop and bring new medicines in order to improve the quality of life and health of people.

In this scenario, it could be important to consider that the research-based pharmaceutical industry plays an important role in ensuring the growth and the competitiveness in the global economy. According to EFPIA, in 2020, this sector invested about 39,000 million of Euro in Research and Development and employed 830,000 people, both upstream and downstream. However, it was hit by the fiscal austerity measures through expenditure cuts introduced since 2010 by most

⁴ EFPIA, *The Pharmaceutical Industry in Figures*, Key data (2021).

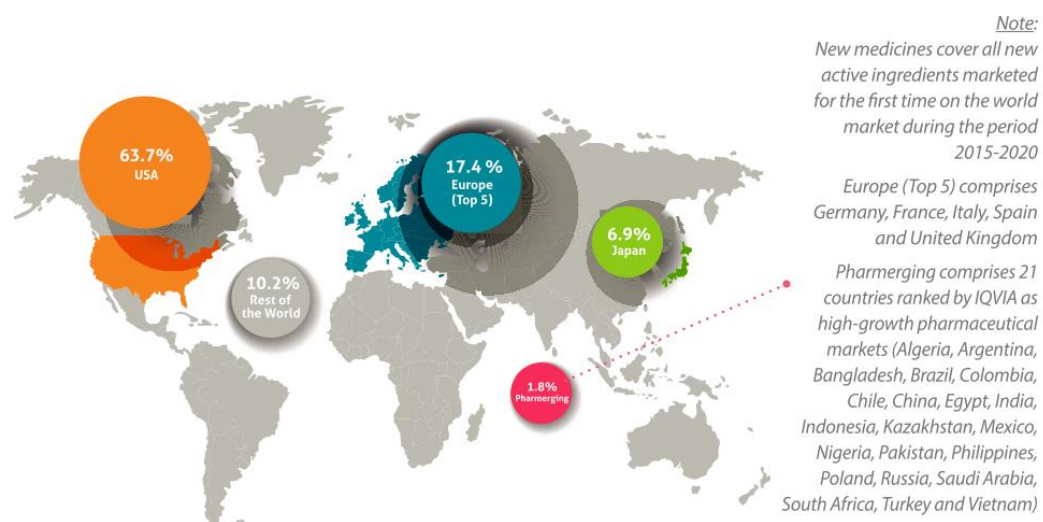
European countries and that allocated less resources to the National Health Service, for the implementation of public finance objectives.

The map below, in Figure 1, shows the geographical breakdown of sales of new medicines launched between 2015 and 2020 supplied by EPFIA. It also highlights the importance of emerging economies that led to a migration of research and economic activities from Europe to those countries. It was shown that Brazil, China and India grew respectively by 11.3%, 4.8% and 10% compared to 5.0% for top 5 EU markets and 4.9% for US market.

In addition, the IQVIA Institute⁵ confirms what was stated in the previous paragraph namely that 63.7% of sales of new medicines were on US market while only the 17.4% in the EU markets.

⁵ The IQVIA Institute is a world leader in using data, technology, advanced analytics, and expertise to help customers drive healthcare forward. It is enabling a more modern and effective healthcare system and creating breakthrough solutions that transform business and patient outcomes.

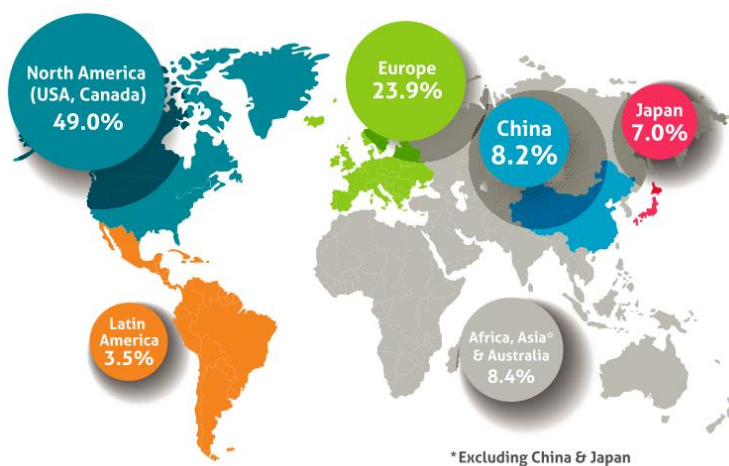
Figure 1. Geographical breakdown (by main markets) of sales of new medicines launched during the period 2015-2020.



Source. IQVIA (MIDAS, 2021).

The world pharmaceutical market sales are approximately € 934,667 million in 2020, with the North American market as the largest one, as shown in the map in Figure 2.

Figure 2. Breakdown of the world pharmaceutical market - 2020 sales.

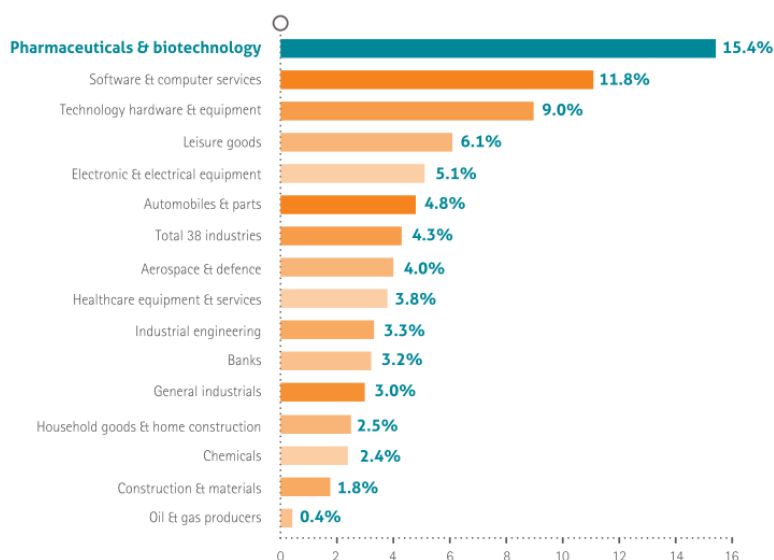


Source. IQVIA (MIDAS), 2020.

As said previously, Research and Development (R&D) are the main activities in the pharmaceutical industry. It is an expensive, risky and long process that not always succeeds and in which not all the substances pass all the stages to become a medicine sold in the market.

In 2019, the EU pharmaceutical industry invested € 37,754 million in R&D with Germany, Switzerland, U.K., France and Belgium as the biggest players. It is also the sector with the highest ratio of R&D investments to net sales, in percentage, followed by the technological sector (see Graph 4).

Graph 4. Ranking of industrial sectors by overall sector R&D intensity (R&D as percentage of net sales - 2019).



Source. The 2020 EU Industrial R&D Investment Scoreboard, EU Commission.

However, this sector is constantly facing the competition of the US market, that led to a shift of activities towards the US. This can be confirmed by the fact that the US annual growth rate in the pharmaceutical R&D expenditure in the years between 2016 and 2020 is almost twice the European one, respectively 7.6% and 3.1%. In addition, as previously said, the rapid growth of emerging economies, where the pharmaceutical market is gradually shifting to, is another threat that the EU needs to face.

Always taking into account the EFPIA data regarding the year 2019, the European pharmaceutical production was about 293,213 million of Euro in which Switzerland, France, Italy and Germany had a value between 54 and 33 million of Euro.

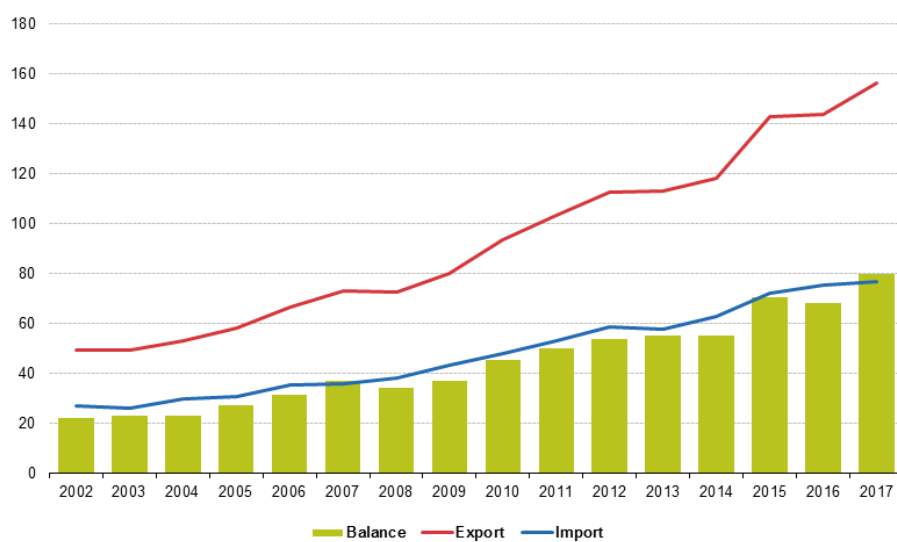
Moreover, it can be said that the research-based pharmaceutical industry is one of the Europe's major employers, generating about three times more employment indirectly (upstream and downstream) than directly. The data states also that those employees are skilled so that the sector can “*maintain a high-level knowledge base and prevent a European “brain drain”*”⁶. This industry registered 823,882 persons employed in 2019, mainly in Germany, France, U.K. and Italy.

Regarding the international trade, the data in the Graph 5 refer to the years between 2000 and 2017 but the increase of exports and the lower level of imports remain the same also with the arrival of the Covid-19 pandemic, with the exception of import and exports peaks in the month of March 2020⁷.

⁶ EFPIA, *The Pharmaceutical Industry in Figures*, Key data (2021).

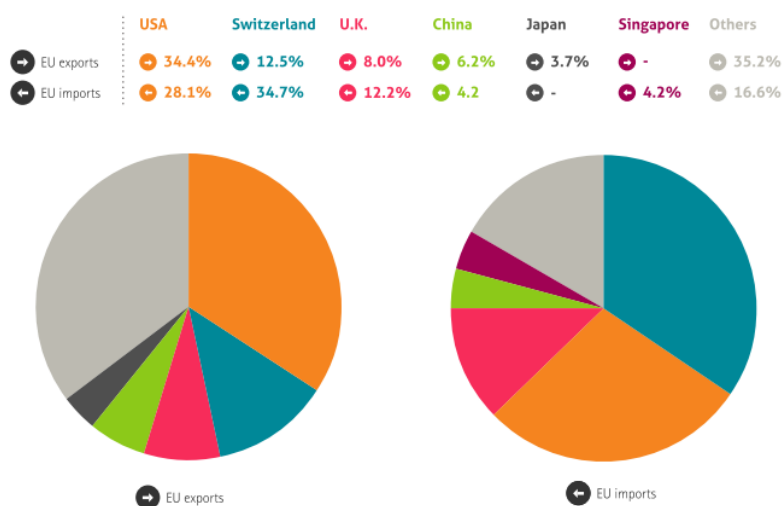
⁷ European Centre for International Political Economy (ECIPE) (2021), *International EU27 pharmaceutical production, trade, dependencies and vulnerabilities: a factual analysis*, <https://www.efpia.eu/media/602699/production-import-dependencies-and-export-vulnerabilities-of-pharmaceuticals-for-the-eu27-final.pdf> [03.11.2021].

Graph 5. EU-28 Exports, Imports and Trade balance in medicinal and pharmaceutical products, 2007-2017 (EUR billion).



Source. Eurostat.

Graph 6. The European Union's top 5 pharmaceutical trading partners – 2020.



Source. Eurostat, COMEXT database⁸ (2021).

What can be highlighted from Graph 6 is that the main destination of extra-European exports of pharmaceutical products in 2020 is the United States, accounting for 34% of the total, followed by Switzerland, the United Kingdom and China. On the contrary, the European Union imports most of those products from Switzerland (35%), the United States and the U.K.

This trend can be confirmed by the largest bilateral trade and investment relationship between EU and the USA. It defines the world economy given that both

⁸ COMEXT is a Eurostat's reference database for detailed statistics on international trade in goods. It provides access not only to both recent and historical data of the EU and its individual Member States but also to statistics of a significant number of non-EU countries.

countries amount to more than 40% of the world GDP and more than 40% of global trade in goods and services. This transatlantic connection led to a value of 353 billion of Euro of exported goods in 2020, that is an increase of 2 billion of Euro with respect to 2018, and it remains strong despite the Covid-19 pandemic.

About 164,000 EU companies export in US and almost 93,000 of them are Small or Medium Enterprises. In the same way, the EU investments in US, and viceversa, are much higher than the ones in China or India. As a result, there is a large contribution to the growth and employment in both parts and *“a third of all transatlantic trade comprises intra-company transfers, a testimony to the deep economic integration between the EU and US markets”*.

Despite this strong relationship, there is no free trade agreement between them but transatlantic trade continues to be based on one of the lowest average tariffs in the world: under 3%⁹. The only source of agreement is the Transatlantic Trade Investment Partnership (TTIP), whose negotiations started in 2013 and ended in 2016 without a conclusion because of obsolete and no relevant directives.

⁹ European Commission, <https://ec.europa.eu/trade/policy/countries-and-regions/countries/united-states/> [24.09.2021]

1.4. THE PARALLEL TRADE PHENOMENON

One topic that deserves the attention related to the field of pharmaceutical imports and exports is the so-called “Parallel Trade”. It was born in the United Kingdom at the beginning of ‘70s but it has evolved through the 2000s and the AIFA (Italian Medicines Agency) provides the following definition:

“The parallel trade in medicinal products for human use is a legitimate form of exchange within the EEA countries (European Economic Area - in Italian SEE, Spazio Economico Europeo), which is made possible by the differential between the purchase price of the medicinal product in the country of origin (lower) and the selling price in the country of destination (higher)”¹⁰.

The parallel trade is therefore considered a form of arbitrage based on the principle of free circulation of goods which is moved by the differences in the price of medicinal products in different countries, by the different national pricing policies and by specific rules adopted by each country with regard to parallel imports. It is estimated to be the 7% of the whole European pharmaceutical market, and to increase by 15% each year, in the last decade.

¹⁰ AIFA, Osservatorio Nazionale sull’Impiego dei Medicinali (2018), *Importazione Parallela ed Esportazione dei medicinali per uso umano, 1° Rapporto Nazionale 2016 – 2018*.

More to the point, there are some specific subjects, the “parallel importers”: they buy drugs in countries where their prices are lower and sell them in other countries where there are higher pharmaceutical prices, usually after having relabeled and translated them in the destination language.

The adjective “parallel” refers also to those importers that are different and independent from the marketing authorization holders, producers or intellectual property licensees. In this way, there is a commercial competition between the owners of products directly distributed and parallel importers, that is named “intra brand competition”: it takes place among distributors and retailers of the same branded product, be it on price or non-price terms¹¹.

The current legislation on parallel trade leads to legal disputes, between pharmaceutical companies and parallel importers: controversies that are based on some common issues - such as intellectual property rights, repackaging, rights on registered trademarks in different countries, product differences among countries, double price between internal market and export, supply limitation from pharmaceutical companies.

¹¹ European Commission (2002), *Glossary of terms used in EU competition policy – Antitrust and control of concentration*, Luxembourg, Office for Official Publications of the European Communities.

In 2003, the European Commission issued a communication¹² to clarify some controversial aspects of pharmaceutical parallel imports. Some European governments encourage this practice as solution to a consistent reduction of the pharmaceutical expenditure. Below, there is a summary of the legislations of the main importer (in red) and exporter (in green) countries (see Figure 3):

Figure 3. A map of the main European countries for pharmaceutical parallel trade.



Source. Gianfrate, F. (2009), Il parallel Trade dei Farmaci in Europa, icom (Istituto per la Competitività).

¹² Commission of the European Community (2003), *Commission Communication on parallel imports of proprietary medicinal products for which marketing authorisations have already been granted.*

- **Importers**

- Denmark: the legislation allows the replacement of national drugs with parallel importers but pharmacists have to inform patients of all the possible alternatives available.
- Germany: in this case, the legislation requires that pharmacies sell at least the 7% of parallel imported drugs at a price that is at least 15% lower than the national one. Doctors have a prescription budget that will penalized them if exceeded. In this way, they are encouraged to prescribe those imported drugs.
- Netherlands: in this country, pharmacists are encouraged to sell imported medicines as they are repaid of the 94% of the national list price. In addition, social security funds put pressure on pharmacists to dispense with parallel imported drugs.
- Norway: as in the case of Germany, here doctors are encouraged to prescribe parallel imported pharmaceuticals and patients have the incentive of asking for the cheapest alternative since the co-payment percentage is significant.
- United Kingdom: pharmacists retain the difference between the price refunded by the government and the purchasing price of the

wholesaler. The government recovers parts of the pharmacists' revenues dependent on the national share of parallel imported products¹³.

- Sweden: in this country, all pharmacies are state-owned. This means that pharmacists must provide the cheaper drug among therapeutically alternative equivalents. In the same way, patients have incentive in asking the cheapest alternative because of the importance of the co-payment. In addition, the marketing authorization of these parallel products are less taxed.

- **Exporters**

- Italy: there are no specific incentives for the pharmaceutical parallel trade, however, there is a simplified procedure for negotiating the price and repayment of medicinal products authorized under the parallel import procedure. It establishes that a company that wants to use the simplified procedure shall submit a price proposal that provides for a reduction of price of at least 7% compared to the public price of the corresponding product already marketed in Italy¹⁴.

¹³ Gianfrate, F. (2009), *Il parallel Trade dei Farmaci in Europa*, icom (Istituto per la Competitività).

¹⁴ AIFA, Importazioni parallele dei farmaci: AIFA pubblica procedura semplificata, <https://www.aifa.gov.it/-/importazioni-parallele-di-farmaci-aifa-pubblica-procedura-semplificata> [08.11.2021].

- Greece: generally, parallel exports are encouraged and health authorities repay taxes paid on exported products.
- Spain, France and Belgium have no specific incentives for pharmaceutical parallel trade but their governments encourage the free circulation of goods.

To sum up, the pharmaceutical parallel import allows the purchase of drugs at lower prices and this constitutes an important advantage for public and private payers, for example healthcare systems or families, in terms of savings, and it is also a profit for parallel importers. However, despite the big monetary advantages and the achievement of economies of scale for parallel importers, this type of trade could be a loss for companies in terms of quality and safety of repackaging, of brand protection and there could be the counterfeiting risk¹⁵.

¹⁵ Gianfrate, F. (2009), *Il parallel Trade dei Farmaci in Europa*, icom (Istituto per la Competitività).

CHAPTER 2. THE ITALIAN PHARMACEUTICAL INDUSTRY

In this chapter, an analysis of the Italian pharmaceutical industry will be introduced, taking into account some of its characteristics and showing the main multinational companies that operate in Italy.

2.1. AN OVERVIEW OF THE ITALIAN SITUATION

The Italian pharmaceutical industry can be considered a strategical asset and excellence in the country's economy but also a leader in the European Union because of its level of production and constant increase in the exports, ranking itself among the ten best exporting countries all over the world.

In our country, there are more than 670 pharmaceutical companies producing medicines and other pharmaceutical preparations (60.3%) or basic pharmaceutical products such as vitamins, antibiotics, salicylic and acetylsalicylic acids, chemically pure sugars and blood derivatives for pharmaceutical use (26.6%)¹⁶.

About a 60% of companies are located in the northern Italy: Lombardy is the region with the highest density (35%), followed by Lazio, Tuscany, Emilia Romagna and Veneto. Those companies are categorized as small or medium enterprises (SMEs),

¹⁶ iCRIBIS (2019), *Dati e numeri del settore farmaceutico in Italia*, <https://www.icribis.com/it/osservatorio/2019/farmaceutico-italia> [05.10.2021].

of which nine out of ten are companies with a share capital (90.1%) with an average of 104 employees and with a strong vocation to export (33%)¹⁷. They are often family businesses, which combine the solidity of this type of companies with the ability to undertake innovative strategies. Strategies that probably do not lead them to carry out research of frontier, indeed they make innovation of “proximity”, increasing the value of products, creating development on the territory and providing very important therapeutic solutions, sometimes joined with multinational companies¹⁸. The wide presence of SMEs spread all over the country allows Italy to rank first in Europe for the number of SMEs.

However, the market is dominated by the so called “Fab13”: 13 medium or large companies with Italian capital. Among them, the “top five” with the highest revenues in 2020 are:

- **Menarini.** Founded by Archimede Menarini in 1886 in Naples, its headquarters are in Florence since 1915 and it operates in the research, production and commercialization of pharmaceuticals and diagnostic products. It is present in 140 countries all over the world with 17 production

¹⁷ iCRIBIS (2019), *Ibidem*.

¹⁸ Saini, V. (2020), *Nel farmaco l'Italia fa davvero sistema*, Gli Stati Generali, <https://www.glistatigenerali.com/industria/nel-farmaceutico-litalia-fa-davvero-sistema/> [13.10.2021].

plants and 3.8 billion of Euro of revenue, divided between Italy (25%) and abroad (75%).

- **Chiesi.** Founded in 1935 and headquartered in Parma, their mission is to be recognized as an international group focused on the research, development and sale of innovative and therapeutic solutions to improve the quality of life of patients. The group registers its direct presence in 27 countries and revenue for 2 billion of Euro.
- **Angelini.** It was founded by Francesco Angelini in 1919 in Ancona as a little pharmaceutical laboratory and in 1950 it moved to Rome where there are its headquarters. It is famous for the launch of pharmaceuticals such as *Tachiprina* in 1958 and *Moment* in '80s and for the acquisition of the Genoese *Amuchina* in 2000 and of *Infasil* from P&G in 2011. It has different plant all over the world and its revenue is about 1,6 billion of Euro.
- **Recordati.** The international pharmaceutical group was founded in 1926 and has its head office in Milan. It has some operating activities in Europe, Russia, Ukraine, Turkey, North Africa, USA, Canada, Mexico, some South American countries, Japan and Australia. It promotes a wide range of innovative pharmaceuticals belonging to different medical areas, including that of rare diseases. In 2020, their revenue is about 1,4 billion of Euro.
- **Bracco.** Founded in 1927, the group is located in Milan and is focused on the trade of diagnostic imaging, above all on contrast agents. It boasts a

heritage of about 2000 patents and invests more than 10% of its revenues in R&D activities every year. Their customers are spread all over the world in 100 countries but, thanks to the quality and the reliability of its products, the most important partners are located in North America, Europe and Japan. In 2020, their revenue amounts to 1,3 billion of Euro.

2.2. DATA AND NUMBERS OF THE ITALIAN PHARMACEUTICAL SECTOR

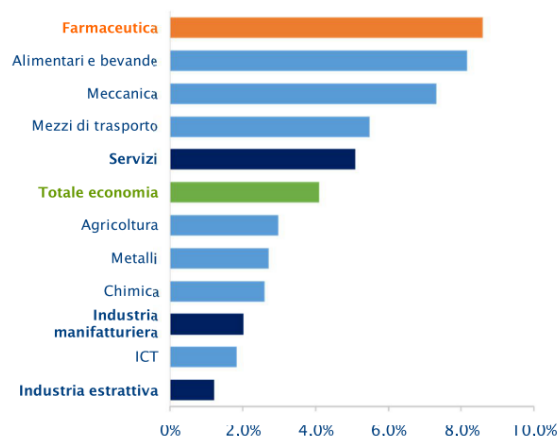
In this part of the chapter, we will take into account the reports of Farindustria, the Italian association of pharmaceutical companies. It was founded in 1978 and it counts with approximately 200 associated companies that operate in Italy and that have Italian or abroad capital.

As previously mentioned, those Italian companies have an important and strategic role for the Country and, thanks to its 34,3 billion of Euro of production value, it is a leader in the European Union along with France and Germany. During those years, above all due to the Covid-19 pandemic, the pharmaceutical companies became fundamental drivers for the growth of our country and for our continent.

2.2.1. Employment

Between 2015 and 2020, the pharmaceutical industry increased the employment (12%) more than other sectors, above all thanks to the increasing importance of R&D tasks. In the sector, there are 67,000 employees¹⁹ and among them the graduates are the 90% that shows a high quality and skills of the human capital, of which 6,600 are employed in Research and Development areas. In recent years and as highlighted in the Graph 7, the pharma is the sector that mostly increase the level of employment: +8.6% versus the 4% of the total Italian economy.

Graph 7. Employment growth between 2014 and 2018.



Source. *Farmindustria (2019), I numeri dell'industria farmaceutica in Italia. Elaboration of Istat and Farmindustria data.*

¹⁹ Farmindustria (2021), *Indicatori Farmaceutici*.

It could be important to say that the so-called “equal opportunities” are a well-established reality in the whole pharma industry: in fact, women represent the 43% of workers and the 52% on R&D, while on other sectors they are only the 29%, and have important roles such as the leadership.

Remaining in the field of occupation, the Italian INPS²⁰ shows that there was an increase of 16% in the employment of young people under 35 years in the pharmaceutical industry and that the 80% of them received full-time open-ended contracts. This positive situation is confirmed also by the fact that this sector is characterized by an innovative model of labour relations that allows to be the first one in the training and adoption of modern and successful tools for company’s welfare, that include conciliation of work and life, education, employees and their relatives’ well-being and assistance to old or non-autonomous familiars²¹.

2.2.2. Investments

Each year, the global pharmaceutical contribution to the invention of new fundamental therapies increase. Innovation and development become one of the most important objects of investments in the world’s economy: it counts with 167

²⁰ INPS: Istituto Nazionale Previdenza Sociale (National Institute for Social Insurance).

²¹ Farmindustria (2021), *Indicatori Farmaceutici*.

billion of Euro of investments per year. The healthcare crisis, due to the Covid-19 pandemic, pointed out the necessity of increasing investments, also accelerating some on-going processes and strengthening the alliance between public and private companies. This can be demonstrated by the increase of 80% of new pharmaceuticals in 2020, with respect to 2019.

It has to be said that the Italian pharmaceutical expenditure and prices of pharmaceuticals are the lowest among European countries and, according to OECD data, it is -20/25% with respect to the first four EU countries.

However, pharma is the third Italian sector for investments: 3 billion of Euro in total for the whole sector, of which 1.7 billion are only for R&D. There is a continuous specialization in biotech pharmaceuticals, vaccines, blood derivatives and advanced therapies and partnerships with universities, SMEs, start-up, excellent centres, non-profit entities (both public or private) are increasing. There are also important investments in clinical studies considering that the 18% of those EU studies are developed in Italy.

2.2.3. Green inclination

It is one of the greenest sector in Italy thanks to the continuous reduction of energy consumptions (-59%) and climate-changing gas emissions (-32%), achieved in a

decade This ecological interest and commitment translates in a competitive element. In addition, most of the environmental investments (44%) made by those companies were aimed at the use of “clean” technologies to reset the pollution from the production processes²². For the next 5 years, companies are involved in reduction and elimination of waste and plastic in their drugs fabrication.

In addition, in Italy, in 1980, updated in 2020, companies established a centralized system that take the name of “**AssInde**”. It is a society composed of Farindustria, Federfarma, Assorfarm and distributors like A.D.F. (*Associazione Distributori Farmaci*) with the purpose of guarantee the proper retire and disposal of expired medicines and, more in general, of pharmaceutical returns.

At European level, in 2015, the pharmaceutical industry signs the “**Eco-Pharmaco Stewardship**” (EPS): a programme aimed at the intelligent and sustainable management of the environmental impact and risks of drugs during their entire life-cycle. It is based on the following key principles: product stewardship, partnership and shared-responsibility, medicine life-cycle, evaluation and re-assessment of environmental risk and work-sharing²³.

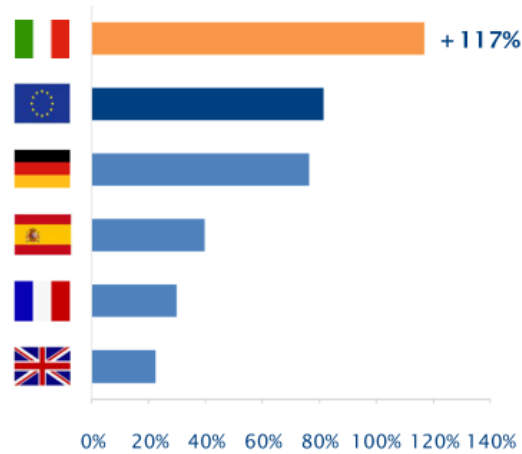
²²Farmindustria (2019), *I numeri dell'industria farmaceutica in Italia*.

²³ EFPIA, AESGP, EGA (2016), *Eco-Pharmaco-Stewardship (EPS) – A holistic environmental risk management program*.

2.3. EXPORT

As it can be seen from the following Graph 8, it registered an important growth in the export (117%) during the decade 2008 – 2018, with respect to the 81% of the overall European Union. This can be explained by the fact that most of the Italian pharmaceutical companies have a foreign capital (57%), with respect to Italian capital companies that are the remaining 43%, and this allow them to stand out in investments and exports with respect to other manufacturing sectors. In this way, Italy becomes one of the first European countries for the presence of drug companies with US and German capital and second for French, Swiss and Japanese ones. Another important aspect, above all nowadays, is that our country is one of the most important hub in the vaccines' production for UK capital companies.

Graph 8. Pharmaceutical Export evolution in EU 2008 – 2018.

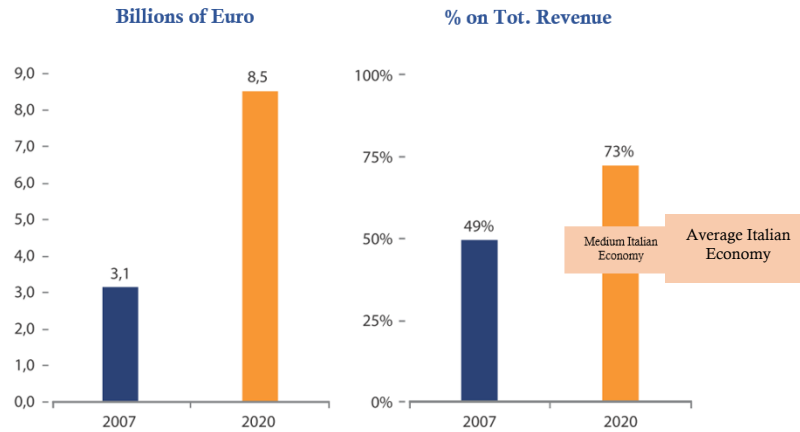


Source. Farindustria (2019), *I numeri dell'industria farmaceutica in Italia*, Data-processing of Eurostat, IQVIA and Istat.

The below Graph 9 shows that drugs companies realize the 71% of their total revenue only thanks to their foreign sales in 2019 and that this data doubled with respect to ten years before: those sales amounted to 3.1 billion of Euro in 2007 and became 8.5 in 2020²⁴. This was possible not because of a perspective of offshoring but this was aimed at the “protection” of new markets that allowed to strengthen the presence of R&D and production activities in Italy.

²⁴ Farindustria (2021), *Indicatori Farmaceutici*.

Graph 9. Sales of drug companies with Italian capital.



Source. *Farindustria (2021), Indicatori Farmaceutici, Data-processing of Nomisma and companies' data.*

The importance and the growth of the pharmaceutical industry can be related to its specialization in some fields, such as vaccines or biotech drugs, that allow to increase investments and to have a wide variety of developing products, also thanks to collaborations with other companies and with national subjects related to innovations. One specialization that should be mentioned is on plasma derived products that is made possible thanks to national companies dedicated to international sales and companies with foreign capitals and that counts with 1,700 employees and with important investments on R&D that are higher than the average of the manufacturing sector.

Italy is also recognized as an international centre for the research and production of vaccines with its scientific traditions and a strong inclination to exports. The latter ensured a positive balance that amounted at 4 billion of Euro in ten years (2010-2020).

2.3.1. The Italian Contract Development and Manufacturing Organization

The Italian pharmaceutical industry has the leadership in Europe of the so-called **Contract Development and Manufacturing Organization (CDMO)**, that is known as third-party production on behalf of big pharma companies. The CDMO is defined as:

“A company dedicated to providing drug development and manufacturing services for the pharmaceutical and biotechnology industries”²⁵.

In other words, it is an organizational model that allows big companies to outsource pharmaceutical production, control and development activities, entrusting them to specialized companies with their own production facilities and laboratories. Certified companies that fall into this category produce pharmaceutical under the pharmaceutical companies' rules as regards facilities, maintenance, quality and

²⁵ Ledesma, P. (2020), *Top 5 Contract Development and Manufacturing Organizations (CDMOs)*, Sofpromed, <https://www.sofpromed.com/top-5-contract-development-and-manufacturing-organizations-cdmos/> [10.11.2021].

safety, but even under the leadership of the parent company they have a primary role in the distribution of the drug in every part of the world²⁶.

As it can be seen in Graph 10, in Italy, this system allows to reach 2,3 billion of Euro of production that are the 23% of the total European production, followed by France and Germany. This data also shows that one-third of the total growth of revenue in Europe is registered in Italy.

Graph 10. Ranking of Pharmaceutical CDMO in Europe.



Source. *Farmindustria (2021), Indicatori Farmaceutici.*

The Italian CDMO has a value of 3,8 billion of Euro, divided between the supply chain (1,76 billion) and the CDMO Italy (2,07 billion). The supply chain consists of production inputs (66%), that are raw materials (active ingredients, excipients),

²⁶ Biselli, D. (2016), *CDMO nel settore farmaceutico: studio di Prometeia e Farmindustria*, Mio Pharma Blog, <https://www.miopharmablog.it/2016/03/cdmo-nel-settore-farmaceutico-studio-di-prometeia-e-farmindustria/> [10.11.2021].

packaging and other stuff; services (24%), such as validation, engineering and technical consulting services, royalties and patents and so on; investment goods (10%), for example property machinery, rents for leased goods and general rents. The pharmaceutical CDMO area demonstrates a great increase of 5.6% between 2019 and 2020 with respect to the – 17.1% of the manufacturing sector in the same period of time²⁷.

Also in the CDMO case, the share of the export is greater than the 70% and the revenue doubled in the last decade. There is a continuous strengthening of exports towards United States that represent the 29% of flows, preceded only by exports towards EU countries that is slightly higher than 50%. This last value decrease with respect to past years and this could be due to the regression of EU members. Moreover, there is the emergence of exports and sales towards Japan, that represents the 3%. CDMOs confirm a great propensity towards investments, that is equal to over two times the manufacturing average. The investments are focused on production lines (42%) and then on upgrading (24%), development (7%), information systems (3%), warehouses (2%) and others (22%)²⁸.

Finally, there are some features that characterize the contract manufacturing and that attract the investments of multinational companies, such as:

²⁷ Prometeia (2020), *Il CDMO farmaceutico. Indagine Prometeia-Farmindustria 2020*.

²⁸ Prometeia (2020), *Ibidem*.

- The productive excellence and quality, flexibility and reliability;
- The value of the human capital, its skills and qualifications that allow to attract foreign investments and its capacity to deal with problems and complexity;
- The importance of the territory that is a strength for the Made in Italy;
- Technologies and facilities that guarantee the efficiency of production processes;
- Environmental sustainability that gives more competitiveness to the offer and that is a fundamental feature in the customers' choice;
- Services, from design and innovation to the marketing and distribution, that allow the third-party to be a responsible in sub-supply contracts;
- Certifications, that grant more value to products to reach new customers and new markets; innovation; that starts not only from the commitment but also from the third-party;
- Supply integration, that could be up-stream or down-stream and that add more know-how and production efficiency²⁹.

²⁹ Quotidiano sanità (2019), *L'Italia è il primo paese europeo per produzione farmaceutica conto terzi. Il report di Farindustria*, http://www.quotidianosanita.it/lavoro-e-professioni/articolo.php?articolo_id=78018 [12.10.2021].

2.3.2 The Big Pharma in Italy

Continuing from the CDMO, the attention should be addressed to “Big Pharma”, listed in Chapter one. They are billionaire companies operating in the production, marketing and distribution of medicines; they act in many parts of the planet, to sell its products and to buy semi-finished products to assemble and research is a fundamental feature for them.

Some of them are present in Italy such as Roche, Novartis, Pfizer, Teva, Bristol Myers Squibb and GSK.

The Swiss **Roche** started its activities in Italy in 1897 and nowadays it counts with 1,200 employees in the establishment of Segrate, near Milano, where that produce and packs solid and in drops formulations, of which the 80% is destined to export. To realize its offer of solutions to prevent, detect, monitor and treat serious illnesses, Roche Italy has three operational societies:

- Roche S.p.A, that places at disposal innovative pharmaceuticals for specific illnesses;
- Roche Diagnostics S.p.A., leader in in-vitro and oncological diagnostic;

- Roche Diabetes Care S.p.A, pioneer in the development of blood sugar monitoring systems and leader in offering diabetes management systems and services³⁰.

In the same way, **Novartis** focused its production in Rovereto and Torre Annunziata, near Napoli, where there is one of the biggest and most important production site for the company and of the entire Italy, and the Division for Innovative medicines near Varese but it counts with other five establishments in our Country³¹.

The American **Pfizer** is present in Italy since 1955. It counts with 2000 employees and 800 million of Euro of revenue in 2020. It has two production locations, Ascoli Piceno, the most important for the preparation of oncological pharmaceuticals, and Catania; its headquarters are in Rome and the Pharmacovigilance, the Clinical Development Oncology, the Global Chemistry Manufacturing and Control and the Regulatory Strategy are in Milan³².

Bristol Myers Squibb employees 700 people in Anagni since 1966 and produces and packages solid oral, biological and sterile drugs³³. Recently, this plant was sold

³⁰ Roche Italy, Official Website, <https://www.roche.it/it/roche-italia/scopri-roche.html> [13.10.2021].

³¹ Novartis Italy, Official Website, <https://www.novartis.it/chi-siamo/novartis-italia> [13.10.2021].

³² Pfizer Italy, Official Website, <https://www.pfizer.it/cont/pfizer-italia-Pfizer-in-Italia/pfizer-in-italia.asp> [13.10.2021].

³³ BSM, Official Website, <https://www.bms.com/it> [13.10.2021].

to the American Catalent, a global leader in the supply of advanced delivery technologies, solutions for the development and production of synthetic and biological drugs, gene therapies and over-the-counter products. Catalent has also consolidated expertise in bringing more products and faster to the market, improving product performance and ensuring a reliable clinical and commercial supply on a global scale.

GSK is a global pharmaceutical company involved in the research, development and production of pharmaceuticals, vaccines and innovative non-prescriptions health products. In Italy, it counts with different plants:

- Siena is one of the specialized centre in the vaccines production, since 1904 thanks to Achille Sclavo, the founder of *Istituto Vaccinogeno Sieroterapico Toscano*, along with Rixensart (Belgium) and Rockville (USA). Since 2008, the GSK Vaccine Institute for Global Health is active in the campus of Siena and it is focused on global challenges of sustainable prevention. The collaborations with the main international bodies engaged in campaigns for awareness and enhancement of access to vaccinations, and with important Italian universities to promote integration between the academic world and private research, make the GSK site of Siena and Rosia a strong global benchmark in the fight against infectious diseases.

- Verona, since 1932 with the foundation of *Società Anonima Italiana Nathan Bompiani*, and since 1990 with the opening of the Glaxo research center, is the plant related to strategic and commercial activities for prescription drugs and vaccines and for all the administrative and support activities for the two mentioned sectors. Since 2009, this is one of the headquarter of ViiV Healthcare, a joint venture with Pfizer and Shionogi that commits to provide and develop new treatments for people living with HIV virus.
- San Polo di Torrile (Parma), acquired in 1984 to meet the local growing demand for pharmaceuticals, is the reference establishment for the production of prescription drugs and their packaging, both for GSK's drugs and for third-party productions.
- Baranzate (Milan), formerly SmithKline Beecham (SB) and first Zambelletti, since 2000 with the merger between SB and Glaxo Wellcome and the consequent creation of GSK, is one of the world's leading companies in the field of Consumer Healthcare, in terms of self-medication and oral health, such as *Polident*, *Sensodyne*, *Voltaren*, *Rinazina*, *BeTotal*, *Polase*³⁴.

The Israeli **Teva**, the world's largest producer of equivalent medicines, operates in Italy since 1992 by acquiring production sites for the production of active

³⁴ GSK Italy, Official Website, <https://it.gsk.com/it-it/chi-siamo/gsk-in-italia/> [13.10.2021].

ingredients and founding in 1996 a commercial subsidiary for the marketing of cancer-equivalent medicines for hospital use. Over the years Teva Italia has become one of the main suppliers of equivalent drugs, specialized drugs and self-medication, both in pharmacies in the territory and in hospital, covering all therapeutic areas, especially the cardiovascular area and chronic diseases, with an innovative focus in the area of the central nervous system. Today, Teva operates with a commercial branch, five sites for the production of active ingredients (Lecco, Varese Milan, Vercelli and Pavia) and one site of finished product (Nerviano, Milan) that allow to cover the entire production cycle of the drugs in the country³⁵.

2.4. THE ITALIAN BIOTECH INDUSTRY

Lastly, the Italian Biotech Industry is worthy of attention, thanks to its contribution in the research and development of pharmaceuticals, vaccines, diagnostic and therapeutically solutions in the Italian healthcare field.

Biotechnologies, described as “*technologies that use living organisms such as bacteria, yeasts, plant and animal cells or parts of them to develop products and processes*” and as “*Key Enabling Technology*” by European Community in 2009, represent real enabling technologies for many industrial sectors, providing through

³⁵ Teva Italy, Official Website, <https://www.tevaitalia.it/> [13.10.2021].

their different applications to multiple increasingly urgent needs of modern society in different fields, such as public health, environmental care, agriculture, food and sustainable development³⁶.

A recent report edited by Assobiotec and ENEA³⁷ recorded a growth in all the main economic indicators and a spread of the activities on the national territory. By the end on 2019, there were 751³⁸ biotech companies in Italy, 20% of which are innovative start-ups, that generate overall a turnover of more than 12 billion of Euro, with an average annual increase of 5%. Among the total biotech companies, 208 of them are dedicated to biotech R&D, 92% of which are nationally controlled: these data open a scenario of important opportunities for early-stage research within the pharmaceutical industry. The biotech sector employs more than 13 thousand of people, 34% of which are involved in R&D activities. The biotech investments in R&D reach 770 million of Euro, grown by 7% with respect to 2016. The 49% of biotech companies is involved in the human health field, which is historically considered the driver for the development of biotechnologies³⁹.

³⁶ Federchimica Assobiotec, *Tecnologie abilitanti per tanti comparti industriali*, <https://assobiotec.federchimica.it/biotecnologie/le-biotecnologie> [09.12.2021].

³⁷ **Assobiotec** is the Italian Association for the Development of Biotechnology, part of Federchimica. **ENEA** is the Italian National Agency for New Technologies, Energy and Sustainable Economic Development.

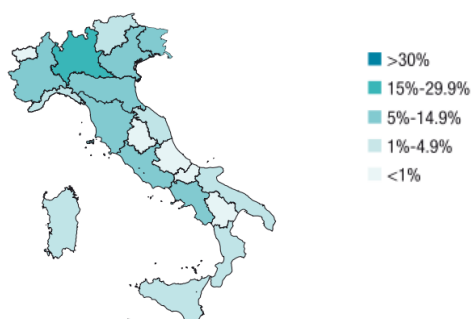
³⁸ ENEA, Assobiotec, (2021), *The Italian Biotech Industry, Economic Update 2021*, https://assobiotec.federchimica.it/docs/default-source/default-document-library/report_assobiotec_2021-final.pdf?sfvrsn=b296ec21_0 [09.12.2021].

³⁹ ENEA, Assobiotec, (2020), *The Italian Biotech Industry, Facts and Figures*, <https://industria.enea.it/osservatorio/documenti/rapporto-biotech-2020-in-inglese> [09.12.2021].

The lack of large Italian capital leading firms led to an inability to express the full potential and value of the industry. However, the real driving force for the growth of the entire sector is represented by micro and small enterprises, the 80%, but also by an increasing number of SMEs that grew by 20% between 2014 and 2019, also thanks to merge and acquisition operations of biotech activities and know-how from start-ups made by companies operating in traditional industries. As it can be seen in Figure 4, the distribution of biotech companies is mainly in the center north of the country, where Lombardy has the 27.8% of the total companies and lead the rank of regions with the highest biotech turnover (45.3%) followed by Latium and Tuscany, Latium the 9.3% and Veneto and Emilia Romagna the 8.8.%. However, the growing share in southern Italy has been particularly significant in the last decade with its 6.9%. Marche Region has only 18 companies that are the 2.6% of the total and its turnover is the 0.16%.⁴⁰.

⁴⁰ ENEA, Assobiotec, (2020), *Ibidem*.

Figure 4. Number of Biotech Firms in 2019.



Source. ENEA, Assobiotec, (2020), *The Italian Biotech Industry, Facts and Figures*.

Moreover, two thirds of the biotech turnover are generated by foreign capital companies which are mainly active in the human health field. The Italian capital companies instead generate more than half of the biotech turnover in the industrial and environmental fields of application.

With regards to Italian biotech firms focused on healthcare, they are 344 and represent approximately the 49% of the total Italian biotech companies. This field generates a preponderant share of the total turnover (75%), it determines the vast majority of the total R&D investments (91%) and holds the 75% of the R&D biotech employees in Italy. In the whole field, there are 375 new projects undergoing study in Italy undertaken by Italian capital companies. The Italian biotech strongly invests in those diseases that lack of adequate therapeutic solutions, among the most important there are oncology and infectious diseases. Greater importance is also given to diagnostic products for human health which

engage 199 companies among the total Italian biotech firms. Looking at geographical framework, the development of new therapeutic approaches and diagnostics is mainly present in the north western area of Italy, driven by Lombardy's small biotech valley which develops the 43% of the national therapeutic research project. The drug discovery and delivery are distributed between the north western area (37%) and center Italy (33%) with Latium's bioscience district as a leader. Moreover, the 60% of companies that develop prophylactic products is located in Latium and Tuscany⁴¹.

In addition, it could be important to talk about Research and Development activities that, if exploited in the right way, could lead to an important growth for the country. In fact, in Italy, there is a growing awareness that the innovation performance can strongly affect the national competitive outcome. However, there are two elements that distinguish the Italian science industry: excellent level of research and limited resources. Although Italian researchers are well known for their excellence and their higher productivity worldwide and the Italian research gives growing contribution to various scientific discoveries all over the world, the Italian development capabilities in this field are limited by a mechanism that pushes out qualified resources but it is not able to adequately attract foreign scientists⁴².

⁴¹ ENEA, Assobiotec, (2020), *Ibidem*.

⁴² ENEA, Assobiotec, (2020), *Ibidem*.

To conclude, referring to the current Covid-19 pandemic, it was observed that firms have faced the new conditions with a good degree of adaptation, despite their reduced size and the vocation to export. Most of them showed a stable turnover, in some cases increased, and stable employment rate and continue their R&D activities protecting the share of industrial activities aimed at innovation⁴³.

⁴³ ENEA, Assobiotec, (2021), *The Italian Biotech Industry, Economic Update 2021*, https://assobiotec.federchimica.it/docs/default-source/default-document-library/report_assobiotec_2021-final.pdf?sfvrsn=b296ec21_0 [09.12.2021].

CHAPTER 3. THE DETERMINANTS OF COMPARATIVE ADVANTAGE IN PHARMACEUTICAL PRODUCTS

This chapter will give a theoretical framework related to the complexity of pharmaceutical products, referring to some literal works written over the years on this particular topic and in view of the empirical part of this work of thesis in the next chapter.

3.1. PHARMACEUTICAL PRODUCTS AS COMPLEX GOODS

The Italian Ministry of Health and the World Health Organization define pharmaceutical products as follow:

*“Any substance or combination of substances presented as having curative or prophylactic properties to human diseases and which may be used in human beings or administered to them for purpose of restoring, correcting or modifying physiological functions by pharmacological, immunological or metabolic action or of making a medical diagnosis”*⁴⁴.

⁴⁴ Ministero della Salute, *Che cos'è un medicinale*, https://www.salute.gov.it/portale/temi/p2_6.jsp?id=3615&area=farmaci&menu=med [15.11.2021].

This definition opens to a wider concept related to pharmaceutical products: the **complexity**. It was described by Costinot as:

*“The number of elementary tasks that must be performed to produce one unit. The more complex a good is, the longer it takes to learn how to perform all tasks, and the larger are the gains from the division of labour”*⁴⁵.

Complex products have numerous characteristics that are subjective and highly differentiated among otherwise similar products⁴⁶. This work will consider some of them in the following paragraphs in order to analyse the distribution of pharmaceutical industry across Italy and its regions.

3.2. THE SOURCES OF COMPARATIVE ADVANTAGE IN COMPLEX GOODS

3.2.1 Human Capital and Specialization

First of all, complexity implies that **workers** must spend a specific amount of time in learning how to perform the task, before being able to successfully complete it.

⁴⁵ Costinot, A. (2009), *On the origins of comparative advantage*, Journal of International Economics, 77, p. 255 – 264.

⁴⁶ Berkowitz, D. et al. (2006), *Trade, Law and Product Complexity*, The Review of Economics and Statistics, 88(2): 363-373.

This topic is also related to the comparative advantage: the theory promoted by Costinot says that:

“Countries with better institutions and/or more human capital per worker and higher educated workers, will produce and export relatively more in the more complex industries”.

Instead, countries with less educated workers and worse institutions, are specialised in the production of less complex goods⁴⁷.

In this view, “countries become what they produce”⁴⁸ in the sense that country’s fundamentals, such as its endowments of physical and human capital, labour, natural resources and quality of its institutions, allow to produce more sophisticated goods and determine relative costs and the patterns of **specialization** that go with them and that will bring higher growth also in the long term, due to highly productive goods, generation of knowledge, differentiation and greater richness.

In addition, Hausmann et al.’s research suggested that the economic performance of a country, including trade, depends on the type of goods in which it specializes. Countries can get stuck with lower-income goods because of the importance of

⁴⁷ Costinot, A. (2009), *On the origins of comparative advantage*, Journal of International Economics, 77, p. 255 – 264.

⁴⁸ Hausmann, R. et al. (2007), *What you export matters*, J Econ Growth, 12:1-25.

externalities that the cost discovery entails, but countries that are able to overcome those externalities can benefit of a higher economic growth⁴⁹.

3.2.2 Intellectual Property Rights protection

Furthermore, complexity should be protected by Intellectual Property Rights (IPRs): they represent an important heritage for companies because it includes intangible assets, such as brand, name, design, know-how, software, that could be essential for the survival of companies in the market and for the preservation of their competitive advantage. The protection of IPRs could happen in different forms:

- Patents, exclusive rights given for the protection of an invention and that have effects only in the territory of registration;
- Copyrights, a form of creative work protection that prevent the use by non-authorized persons;
- Trademarks, an exclusive and territorial right on the use of a sign in relation to goods or services for which it was registered and that allows its owner to prevent others from using identical or similar signs.

⁴⁹ Hausmann, R. et al. (2007), *Ibidem*.

Nowadays, due to globalization and internationalization strategies, it is essential for companies to extend the protection not only to the country of origin but also to countries where goods are exported and marketed, where is planned to do so or where the counterfeiting is high⁵⁰.

In this context, IPRs regime in destination countries influences the decision of firms, active in a certain country, between procurement from related parties and from independent suppliers. In fact, IPR protection becomes the biggest challenge of globalized R&D because it was found a lack of this protection in emerging markets, and also technology complicates the relation with suppliers and makes it optimal to vertically integrate. As a matter of fact, goods that require more complex tasks are difficult to copy and reproduce and then create less contravention problems.

Therefore, IPR protection should be more crucial in the outsourcing of less complex and so easily imitable goods. However, a firm can lose important and sensitive information and profits when it decides to share intentionally complex technologies with its partners with IPRs protection low or absent. In this case, intermediates containing a more complex technology are more sensitive and associated with a larger loss if imitated because the technology is more valuable. Here, IPRs

⁵⁰ Cristofori, E., *L'importanza di tutelare la Proprietà Intellettuale*, MercatoGlobale.it, <https://www.mglobale.it/altre-tematiche/tutte-le-news/l-importanza-di-tutelare-la-proprietà-intellettuale.kl> [07.12.2021].

protection is particular important to reduce imitation risks and to promote outsourcing of more complex goods⁵¹.

According to Naghavi et al., in the relationship between IPRs protection and product complexity, it came out that more complex tasks mitigate the need for IPRs protection when firms outsource to independent suppliers: in fact, firms tend to outsource more complex products in countries with relative less stringent IPR regime because complexity provides a shelter against imitation and decoding, otherwise possible with simpler goods⁵².

At the same time, IPRs protection increases its importance in outsourcing complex products when technology is involved in the sharing. Indeed, IPRs protect firms from the risk of losing their technology, whose value increases with complexity. This is to say that, in a weak IPRs environment, costly intangible assets, included in complex products, can be effectively protected against imitation only inside firm boundaries.

In this regard, it can be said that stronger IPRs in a destination country encourage technology transfer by multinational firms and that:

⁵¹ Naghavi, A. (2015), *Ibidem*.

⁵² Naghavi, A. (2015), *Ibidem*.

- For outsourcing involving technology share, IPR protection promotes outsourcing of more complex inputs to a destination country by guaranteeing the protection of their shared valuable technology;
- For non-technology-related outsourcing, IPR protection attracts the outsourcing of less complex products that are more inclined to imitation⁵³.

Furthermore, it was studied that a strengthening of IPRs in developing countries increases the value of exports, in terms of quantity, of developed countries in patent-sensitive industries. This effect could be particularly visible for industries that rely heavily on patent protection, such as pharmaceutical and medicinal products or professional and scientific equipment⁵⁴.

3.2.3. Quality of Institutions

Last but not least, talking about complex products and international trade, another factor that should be considered is the **quality of institutions**, measured by the Institutional Quality Index (IQI). It is the index that measures the quality of public institutions at regional and provincial levels and it is measured with values between zero and one.

⁵³ Naghavi, A. (2015), *Ibidem*.

⁵⁴ Ivus, O. (2010), *Do stronger patent rights raise high-tech exports to the developing world?*, *Journal of International Economics*, 81, 38-47.

With regard to this topic, a sentence of two economists, Anderson and Marcouiller, states:

*“Bad institutions located in the importer’s country deter international trade because they enable economic predators to steal and extort rents at the importer’s border. Bad institutions located in the importer’s country raise international transaction costs and deter international trade”*⁵⁵.

This can be explained by simply saying that countries that have good institutions tend to export more complex products and import more simple ones. Institutions can exert a strong influence on trade via production costs, reminding to comparative advantage, rather than through international transaction costs. Otherwise, when law enforcement authorities are ineffective, there could be corrupt government officials and other, leading to the exporter’s risk of not receiving payment and the importer’s risk of not receiving the shipment.

The above concepts can be based on a theory that suggests that the quality of domestic institutions matters for the participation of a country in international trade and for its national production and that foreign investors are assured that they can

⁵⁵ Berkowitz, D. et al. (2006), *Trade, Law and Product Complexity*, The Review of Economics and Statistics, 88(2): 363-373.

stipulate a contract by using legal institutions in that country⁵⁶. This model can be represented by four main points:

- The exporter's risk of non-payment is effectively offset by contractual means.
- Good institutions in the exporter's country are critical for counterbalance the importer's risk of receiving an inappropriate shipment.
- It is more difficult for institutions in the exporter's country to enforce trade contracts for complex products than for simple products. This is because of the amount of characteristics that complex products have and that make it impossible to fully stipulate an order for these products in formal contracts, rendering them highly incomplete. Therefore, it will be difficult for institutions to determine the breach or the fulfilment of a contract for complex goods.
- Companies that want to buy inputs and outsource on domestic markets also depend upon their domestic institutions to limit stealing and corruption and to enforce contracts⁵⁷.

⁵⁶ Berkowitz, D. et al. (2004), *Legal Institutions and International Trade Flows*, Michigan Journal of International Law, 26(1), 163-198.

⁵⁷ Berkowitz, D. et al. (2006), *Trade, Law and Product Complexity*, The Review of Economics and Statistics, 88(2): 363-373.

Based on those predictions and on evidence, it can be affirmed that countries that have high-quality institutions tend to export more complex products and import more simple ones. In order to increase the legal institutions' quality, countries can adopt some policies that will have important effects on trade by dissuading predators in the importer's and exporter's country, by encouraging exporters to make a good-faith effort to fulfil their contractual obligations and by allowing producers to outsource cheaply within their domestic markets, thus influencing comparative advantage⁵⁸.

In addition, high quality institutions and goods' complexity are important also for the fulfilment of a contract and the avoidance of litigations: the more complex they are, the higher is the probability that shipments received by an importer do not meet the expectations and this confirms the fact that the complexity of a product leads to contracts' incompleteness. In this case, institutions affect the exporter's ability to outsource on the domestic market and sell on world market. However, domestic and international institutions can interchange for each other, especially for countries in which there are low-quality institutions. In this way, the implication could be that political actors can indirectly influence the industrial structure of the country, topic particular important for developing countries⁵⁹.

⁵⁸ Berkowitz, D. et al. (2004), *Ibidem*.

⁵⁹ Berkowitz, D. et al. (2004), *Ibidem*.

To sum up, the complexity of goods may play an important role as a self-defence mechanism against the violation of goods. Firms recognize IPRs as a significant factor in their decision regarding the location of outsourcing when the contract involves technology transfer. In this case, firms can decide to outsource complex products to localities where their IPRs protection system is strongly recognized. Here, IPRs work to protect multinational companies against the dissolution of their knowledge-based intangible assets⁶⁰.

Similarly, the role and quality of institutions are important: higher quality legal institutions located in the exporter's country enhance international trade in complex products and enable the exporting country to cheaply and quickly enforce contracts and resolve business disputes by reducing the probability of delaying on the production chain, and this in turn reduces the production costs and raises a country's comparative advantage in complex products⁶¹.

⁶⁰ Naghavi, A. (2015), *Intellectual property rights, product complexity and the organization of multinational firms*, Canadian Journal of Economics, Vol. 48, No. 3.

⁶¹ Naghavi, A. (2015), *Ibidem*.

CHAPTER 4. AN EMPIRICAL MODEL OF THE LOCAL DETERMINANTS OF THE PHARMACEUTICAL INDUSTRY TERRITORIAL DISTRIBUTION IN ITALY

This last chapter will present the analysis of the Italian pharmaceutical industry distribution across the country, based on some of the above sources of the comparative advantage. The origin of data will be explained along with the results.

4.1. THE OBJECTIVE AND THE DATA FOR THE ANALYSIS

The purpose of this study is focused on the estimation of the importance of human capital and institutional quality in the localization of pharmaceutical manufacturing and biotechnology industries in Italy. The idea behind is the one promoted by Costinot and so that the combination of a specific human capital and a proper level of institutional quality will favour the specialization and the localization of a sector or an activity in a certain location.

In this sense, the dataset examines the twenty Italian regions in a period of time ranging from 2007 to 2016, due to the availability of data. The model considers three main variables:

- **Number of workers.** The dataset contains data on persons employed and local units in the pharmaceutical and biotechnology industries and also in

manufacturing and business services sectors as a whole. The information origin comes from the ASIA – ISTAT archive, namely the Statistical Register of Active Companies, in Italian the “*Registro Statistico delle Imprese Attive*”⁶².

- **Tertiary education.** The dataset, coming from ISTAT archive⁶³, takes into account the population aged 30 – 34 years at education levels 5 and 6 (ISCED97 – International Standard Classification of Education) as a percentage of the population in the same age group (total). The definition of "tertiary education", at these two levels, includes degrees of four years or more (old system or master's degree/single cycle degree), three-year first level degrees, two-year second level degrees, two/three-year university degrees, Schools directed to special purposes, para-university schools and diplomas of Academy of Fine Arts, Higher Institute of Artistic Industries, Academy of Dramatic Art, Fine Dance Academy, Conservatory Refinement, Specialization Institute of music, Academic diploma of high artistic and musical training and Phd programs.
- **Institutional Quality Index (IQI).** IQI is the index that measures the quality of public institutions. Among the five dimensions - corruption,

⁶² ASIA – Istat, *Registro Statistico delle Imprese Attive*, <https://www.istat.it/it/archivio/216767> [10.12.2021].

⁶³ Istat, *Indicatori Territoriali per le Politiche di Sviluppo – Istruzione e Formazione*, <https://www.istat.it/it/archivio/16777> [10.12.2021].

government effectiveness, rule of law, voice and accountability and regulatory quality⁶⁴. The empirical model takes into account the general index, as the average of all dimensions, but also the two following dimensions, because they better represent the institutional quality, and they are more capable of generating attraction or not with respect to the establishment of pharmaceutical complex production activities in certain areas⁶⁵:

- Corruption, that refers at crimes against the Public Administration, the number of local administrations overruled by federal authorities and the Golden-Picci Index, which estimates the corruptive risk, calculating the relationship between the physical value of realized public works and the inputs used to realize them, over a long period of time⁶⁶.
- Government Effectiveness, which measures the endowment of social and economic structures in Italian provinces and the

⁶⁴ Nifo, A., Vecchione, G., *Institutional Quality Index*, <https://sites.google.com/site/institutionalqualityindex/dataset?authuser=0> [12.12.2021]

⁶⁵ The empirical model does not consider the other three dimensions of Institutional Quality because their level of significance and their field of application were not relevant for the focus of this study and for Pharmaceutical and Biotechnology industries.

⁶⁶ Zatti, A., Procaccini, R. (2020), *Anticorruzione e buon andamento della pubblica amministrazione: spunti e riflessioni*, Pavia University Press, 2019. – 128 p.

administrative capabilities of provincial and regional governments in terms of health policies, waste management and environment⁶⁷.

The choice of these two dimensions is due to the connection between Pharmaceutical industry and the efficiency of public sector. In fact, Public Administration, with its proper authorities, and pharmaceutical-biotechnology industry go “*hand in hand*”: their cooperation could lead to an increase in innovation, training, generational turnover and excellence of these two fields.

4.2. THE EMPIRICAL MODEL

For the purpose of the thesis, all the data, mentioned before, were collected and, at first, elaborated on Stata, a statistical software for data science. The new output has been worked on Gretl, an open source package for statistical and econometrics analysis, through the Ordinary Least Squares Method (OLS) and results will be presented in the next paragraph.

⁶⁷ Casamonti, M., Liaci, S. (2021), *La qualità delle istituzioni pubbliche nelle province italiane*, Osservatorio sui Conti Pubblici Italiani.

After different combinations of variables and data, the two most significant dependent variables were the products of the two following formulas, that refers to the average weight of these variable in Italy:

- **Share of Pharmaceutical Workers in Italy** = Share of workers in Pharmaceutical industry in a region “R” / Share of workers in Pharmaceutical sector in Italy.
- **Share of Pharmaceutical and Biotechnology Workers in Italy** = Share of workers in Pharmaceutical and Biotechnology industries in a region “R” / Share of workers in Pharmaceutical and Biotechnology sectors in Italy.

They refer to the standardization of regional employees on the relative share of employees to the fields of Pharma and of Pharma and Biotech together in Italy, respectively.

Moreover, on Gretl, dummy variables were created to represent subgroups of periods of time (years) and of geographical areas, giving the correspondence of Area 1 with northern Italy, Area 2 with central Italy and Area 3 with southern Italy.

In addition, the models consider as independent variables tertiary education, corruption, government effectiveness and the average IQI, for the institutional quality. Lags have been created for all the regressors to better study the relationship between all the variables, that are renamed as “*variable name_1*”.

4.3. RESULTS

In order to understand the relationship between tertiary level of education, Institutional Quality Index and the presence of human capital employed in pharmaceutical industry, different models with different variables have been made in Gretl, as mentioned before.

Table 1. Ordinary Least Squares Results from Gretl.

		Model 1		Model 2		Model 3	
		Corruption_1	Tertiary_1	Government_1	Tertiary_1	IQI_1	Tertiary_1
Share of Pharmaceutical Workers in Italy	Coefficient	-0,582 *	0,060 ***	0,832 **	0,053 ***	-0,475	0,056 ***
	S.E.	(-0,323)	(0,014)	(0,380)	(0,014)	(0,354)	(0,014)
	R-squared	0,34		0,35		0,33	
Share of Pharmaceutical and Biotechnology Workers in Italy	Coefficient	-0,591 *	0,058 ***	0,805 **	0,052 ***	-0,479	0,055 ***
	S.E.	(-0,310)	(0,014)	(0,365)	(0,013)	(0,339)	(0,013)
	R-squared	0,34		0,35		0,33	

Note. The estimated models consider 180 observations, for 20 regions and 10 years, and include fixed effects for years and area dummy variables.

In Table 1, there are three main estimated models where the stars indicate the statistical significance for each variable, given by the correlation between coefficient and Standard Error (“S.E.” in Table 1) and this will be the main focus of this work.

In this sense, tertiary education is the most relevant variable in all models and this means that the level of education of the population has a positive impact on the

labour share of pharmaceutical and biotechnological industries. A middle level of significance is given by government effectiveness, referring to the endowment of social and economic structures. Finally, the corruption is the variable that has little significance over the labour share but, its coefficient alone denotes that, if the level of corruption increases by 1 point, the employment in both pharmaceutical and biotechnology industries will decrease. The average IQI is not taken into account due to its low level of significance and this focuses the attention on the other two dimensions.

The variation of dependent variables can also be explained by the values of R-squared, the coefficient of determination, also called “indicator of the goodness of fit”: it is a statistical value that allows to understand if a linear regression model can be used to make predictions. It is mainly used in multiple regression models, that is with more than one independent variable, as in this case study. It measures also the strenght of a linear relationship between the independent variables and the dependent one. Stronger relationships indicate less dispersion of data around the regression line.

In this respect, the Table 1, shows values of R-squared very similar to each other, all around the 33-35% of variability of dependent variables. However, despite these values are not very high, the model with the highest is the second one, where

government effectiveness and tertiary education have the highest levels of
significativity.

CONCLUSIONS

Recently, the pharmaceutical industry has been the focus of studies and critics due to the Covid-19 pandemic but the purpose of this work was to detect the importance of human capital, education and institutional quality in the localization of pharmaceutical and biotechnology industries.

The Italian pharmaceutical industry demonstrates to have importance in the European scenario. It is a strategical asset for the Italian economy and it has a leader position for its level of production and for an increasing level of exports, that allows it to be one of the main exporter countries in the so-called Parallel Trade Phenomenon. Important are also the expenditure in Research and Development activities and the presence of multinational companies, known as “Big Pharma”, that allow the country to specialized in some important fields.

In order to satisfy and explain the initial question of this elaborate, the theory suggests that pharmaceuticals can be considered complex goods and, as such, their comparative advantage could depend on some variables, mentioned above. In this regard, the comparison of data gathered enabled the identification of three main indicators: corruption, government effectiveness and the average Index of Institutional Quality.

Crossing all information and elaborating them, the results highlight that a higher level of corruption in regional governments will decrease the share of workers in pharma and biotech industries. Meanwhile, a better quality and efficiency of regional governments and of public expenditure, also in healthcare, is associated with a higher share of dependent variables. These increase is also registered through the significance of tertiary education, that allows the concentration of educated workers in pharma and biotech sectors.

Therefore, it could be important for regions to focus on the adoption of policies in order to improve their institutional quality, the level of education of their population and the consequent spread of pharma and biotech industries in their territories. In this regard, regions should promote policies that enhance the reliability, the fairness and the efficiency of their administrations and that decrease the level of corruption, for example by increasing the transparency of public decisions, simplifying public administration procedures and increasing the level of independence of the judicial system. Other policies should also focus on accumulating human capital and retaining it in regional territories, enhancing its skills and providing working and growth opportunities, in order to avoid the so-called “*brain drain*” towards more flourishing areas that offer broader perspectives.

This could lead to the conclusion that both the institutional quality, considered in terms of corruption and government effectiveness, and educated human capital will

favour the specialization, the localization and the growth of pharmaceutical and biotech industries in certain areas.

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