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The European Pharmaceutical Industry in a Global Economy:

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Abstract

The pharmaceutical industry is one of the most competitive sectors in the European Union. With its substantial investments in research and development, this industry represents a key asset for the European economy and a major source of growth and employment. However, despite the importance of the pharmaceutical sector for the European Union, few researchers have attempted to assess the determinants of the EU exports of pharmaceuticals. This paper aims at filling the aforementioned gap by examining what drives EU exports of pharmaceuticals. In order to tackle this question, this paper has derived hypotheses from the Gravity Model of Trade and the relevant academic literature on pharmaceuticals. Based on an econometric analysis, the research sheds light on the complex interaction of factors influencing the EU exports of pharmaceuticals. The paper finds that the protection of intellectual property in the receiving countries, their economic size, the importance of their health sector, and the quality of infrastructures constitute major drivers to the EU exports of pharmaceuticals. On the contrary, the research shows that transports costs as well as tariff barriers and non-tariff barriers tend to hinder the EU exports of pharmaceuticals.

Keywords: Pharmaceutical industry, Exports, Gravity Model, Intellectual Property Rights, Non-tariff barriers, Free Trade Agreements.

JEL codes: F14, C23.

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1. Introduction

The 2013 Competitiveness report of the European Commission entitled “Towards knowledge driven reindustrialisation” highlights some of global issues that the European Union needs to address, namely, the decreasing weight of the EU industry in the world, the loss of competitive advantages in many sectors and the growing EU-USA productivity gap (European Commission, 2013(a), p 13). In light of those challenges, the report argues that the European Union should find innovative solutions to maintain its position as a major producer of knowledge in key enabling technologies and vital high-tech sectors. Being one of the top performing industries of the European Union, the pharmaceutical sector has a crucial role to play in fostering EU growth and competitiveness. With its annual output of € 220 billion and its substantial investment in R&D compared to other manufacturing sectors, the EU pharmaceutical industry is a strategic asset to the EU economy (European Commission, 2014). According to the 2012 EU Industrial R&D Investment Scoreboard, the pharmaceutical and biotechnology sectors represent 17.7% of business R&D expenditures in the world (European Commission, 2012(a), p 43). The pharmaceutical industry is also of crucial importance for the EU which is the major world trader in medicinal and pharmaceutical products. In 2012, the extra-EU-27 exports of pharmaceuticals accounted for € 106 353 027 millions (European Commission, Market Access database, 2014).

However, despite the importance of this sector for Europe, the literature on the EU exports of pharmaceuticals is rather scarce. Most of the research on the pharmaceutical industry concerns its impact on the health sector (for few examples see Rhee, 2008; Mills, Hanson & McPake, 2002) and the respect of competition rules by pharmaceutical companies (Roberts, 2009; Danzon & Chao, 2003). Furthermore, the research on the drivers of the EU exports of pharmaceuticals is almost non-existent in the academic literature. The aim of this paper is therefore to address the aforementioned gap by analysing the main determinants of the EU exports of pharmaceuticals using the gravity model of trade. Beyond its academic contribution, the ambition of this research is to enhance our knowledge of the factors driving the EU exports of pharmaceuticals in order to remain a major world exporter in the future. This research appears all the more necessary in a context of economic crisis and slow internal demand where trade is expected to play a crucial role in fostering EU growth and competitiveness.

Indeed, the European Commission predicts that “the contribution of external demand to economic growth is bound to increase in future, as 90 % of global economic growth by 2015 is expected to be generated outside Europe, a third of it in China alone” (European Commission, 2012(b), p. 4).

The literature on the gravity model of trade will serve as a theoretical foundation for this research. The paper uses a combination of quantitative and qualitative research methods to examine the determinants of the EU exports of pharmaceuticals. The econometric analysis enables us to test the statistical significance of a wide range of variables on the EU exports of pharmaceuticals namely, the protection of intellectual property, the level of healthcare expenditure of the partner country, the existence of a Free Trade Agreement, the transport costs, the health status and the Gross Domestic Product (GDP) of the receiving country.

The remainder of the paper is organised as follows. The following section offers an overview of some of the main barriers for the pharmaceutical industry based on official reports. The third section presents the theoretical framework which combines insights from the Gravity Model of Trade as well as the relevant literature on the subject. The fourth section of this paper provides an econometric analysis of the determinants of the EU exports of Pharmaceuticals. Finally, the fifth section concludes on the main drivers and obstacles to the trade of pharmaceuticals.

2. Literature review on the main exports barriers for the pharmaceutical sector

The aim of this part is to provide a qualitative analysis of some of the main barriers related to the trade of pharmaceuticals. The findings of this part are based on a review of the official reports related to the pharmaceutical industry.

2.1. Tariff barriers

Since 1947, multilateral negotiations through the World Trade Organization as well as bilateral and regional trade agreements have contributed to lower drug tariff. Today, most of the OECD members have zero tariffs for pharmaceutical products as a result of the

Uruguay round (1986-1994) (Kiriyama: OECD, 2011, p. 43). However, emerging countries such as China, India, Russia, MERCOSUR and ASEAN countries still impose high tariff on pharmaceutical imports from the European Union (European Commission, 2011(a), p. 9). For instance, the report from the European Commission cited above indicates that a tariff of 10% is applied to EU generics containing penicillin and their derivatives in India (p. 9). These high tariffs imposed by some emerging countries are a source of concern for the EU pharmaceutical industry as it increases the price of their products overseas and limits the access to medicines (interview EFPIA, February 2014). According to the OECD, 66.8% of the revenues gained from tariff on pharmaceuticals are earned by the 10 non-OECD members in 2008 (Kiriyama, op. cit, p. 44). The weighted average tariff in these countries was 7.58% in 2008 (ibid, p. 44). Table 1 illustrates more in detail the difference of tariff on active pharmaceutical ingredients and finished products applied by lower, upper-middle income and high income countries.

Table 1: Distribution of tariff rates by country groups for active pharmaceutical ingredients and finished products containing other antibiotics.

a) Active pharmaceutical ingredients containing other antibiotics (300320)

Tariffs rate (%)	Number of countries (n= 140)	Percentage of all countries	Low-income countries	Lower-middle-income countries	Upper-middle-income-countries	High-income countries
0	70	50%	22	18	13	17
0-5	28	20%	9	11	6	2
5,0-10	29	21%	8	9	10	2
10,1-20	10	7%	3	4	3	0
> 20	3	2%	1	2	0	0
* MEAN - 4,46 %; MEDIAN - 0,50 %						

b) Finished products containing other antibiotics (300420)

Tariffs rate (%)	Number of countries (n= 148)	Percentage of all countries	Low-income countries	Lower-middle-income countries	Upper-middle-income-countries	High-income countries
0	64	43%	21	14	12	17
0-5	35	24%	11	14	7	3
5,1-10	34	23%	10	10	10	4
10,1-20	13	9%	3	7	3	0
> 20	2	1%	1	1	0	0
* MEAN - 5,14 %; MEDIAN - 3, 5 %						

Source: Olcay & Laing (2005, p. 27)

The report conducted that Müge Olcay and Richard Laing (2005, p. 38) shows that even though the revenues generated from the levies on medicines are quite small, these tariffs may limit the access of the poor and the sickest to affordable medicines.

2.2. Non-tariff barriers

Due to their impact on the health sector, pharmaceutical products are highly regulated. Although most of the regulations and standards are justified, they may significantly affect the trade of pharmaceuticals. It is therefore essential to ensure that the measures are strictly necessary and that do not represent discriminatory or disproportionate regulations or standards. Non-tariff barriers (NTBs) are one of the most important sources of concern for the pharmaceutical sector. These NTBs can take several forms ranging from registration, certification, or government policies concerning the price and the reimbursement of medications (European Commission, 2011(a), p. 10). Registration barriers can represent a serious obstacle to the trade of pharmaceuticals. Indeed, additionally to the standards set by European Medicine Agency, EU producers have to comply with many requirements to obtain an authorization to export their products (ibid, p. 11). These certificates can differ from one country to another which increases the administrative burden on pharmaceutical companies. In emerging economies such as China, India, Russia, and Brazil, the EU has to comply with different requirements and market authorizations which are often very long to obtain (ibid, p. 11). Pharmaceutical companies are also affected by non-tariff measures (NTM) in developed countries such as Japan and the United States. For instance, the regulatory differences between the United States and Europe induce an additional cost of 9.5% for EU exporters (Berden, François, Thelle, Wymerga, Tamminen, 2009, p. 30). Moreover, non-tariff barriers in Japan are estimated to increase the cost of EU pharmaceutical exports by 22 percent (Sunesen, Francois and Thelle, 2009, p. 10).

This is why, in addition to the discussions launched at multilateral level, the European Union has started many bilateral negotiations with countries to eliminate non-tariff barriers with its key partners. According to a recent report, a reduction of 2% of non-tariff barriers in Japan could boost EU exports of pharmaceuticals by 60% (Sunesen, Francois & Thelle, 2009, p. 10). Moreover, the annual income gain from an EU-US Transatlantic Trade and

Investment Partnership (TTIP) for the EU chemical cosmetic & pharmaceutical sector is expected to vary between $ 7.1 and 9.2 billion (Koen et al, 2007, p. 26).

2.3. The protection of Intellectual Property Rights

Since the Pharmaceutical industry is very research intensive, the protection of Intellectual Property is crucial to preserve the competitiveness of this industry. Indeed, the lack of enforcement of IPR creates disincentives for innovation and prevents pharmaceutical companies to recoup their investments in R&D. A study conducted by Lanjouw in 2005 also confirms that stronger patent protection will encourage companies to launch more rapidly new drugs in the market (cited in Kiriyama: OECD, p 52). Counterfeiting medicines[1] and Piracy are also considered as one of the most important issue by the EU pharmaceutical industry. Indeed, counterfeit medicines create a disincentive for originators companies to invest in R&D to develop new drugs and threaten the competitiveness of this industry. According to a report from European Alliance for Access to safe medicines, the volume of counterfeiting seized in Europe has considerably increased in the latest years. For instance, in 2006, 2.7 million of counterfeit products were found which represent more than 8 times the volume discovered in 2004 (p. 10).

Three countries can be considered as problematic regarding the respect of Intellectual Property Rights namely China, India and Canada (European Commission, 2011, p.15). In China, concerns related to the protection of Intellectual Property Rights do not arise from the lack of regulation on IPR but from the inadequate enforcement of the regulation on IPR which facilitates the production and selling of counterfeiting. The cost of counterfeiting drugs for pharmaceutical groups in China represents 10% to 25% of their annual sales (ibid, p. 94).

The EU pharmaceutical industry is also concerned with the insufficient enforcement of IP regulation in India (UK Intellectual Property Office, 2013, p. 9). Indeed, once pharmaceutical companies have applied for a patent, they often have to wait two years for the patent to be examined and approved (Kiriyama, 2011, p. 53). Moreover, the Indian government and the

[1] According to the European Alliance for Access to safe medicines (2008): “A medicine is counterfeit when it is deliberately and fraudulently mislabelled with respect to its identity, history and/or source” (p. 8).

Supreme Court apply a restricted interpretation of Intellectual Property Rights to facilitate the replacement of more expensive life-saving medicines by cheaper generic drug. For instance, in 2013, the Supreme Court in India has rejected a plea from Novartis to patent the cancer treatment drug “Glivec”. However, this situation can hamper the competitiveness of drug manufacturers who have to bear the high costs of R&D to develop new drugs but may not be able to fully recoup their investments due to the lack of Intellectual Property Protection.

Compared to many developed countries, Canada is lagging behind in the protection of Intellectual Property Rights (European Commission, 2013(c), p. 1). Indeed, the Canadian law on data protection only applies to a small subset of new medicines. Thus, only drug ingredients that are contained within a medication for the first time will receive benefit from data protection (Kierans, Wagner, Thill-Tayara, 2011, p. 3). This means that a medicine combining several drug ingredients will not be subject to Intellectual Property Protection unless it contains at least one innovative component (ibid). The weak protection of intellectual property rights in Canada compared to other developed countries is an important source of concern for the EU pharmaceutical industry. The official reports show that the protection of intellectual property rights represents an major challenge for the European pharmaceutical industry in the different countries mentioned above. This is why it would be interesting to analyze in this paper how the level of intellectual property rights in different countries affects the EU exports of pharmaceuticals.

3. Theoretical framework

3.1. The gravity model of trade

The gravity model of Trade serves as a theoretical framework for this paper. This model has become more and more popular in international trade literature. This approach provides a powerful tool to analyse trade flows between countries and the trade impact of different policies. Moreover, according to Learner and Levinsohn (1995), the Gravity model of Trade has delivered “some of the clearest and most robust findings in empirical economics” (cited in Shepherd, 2013, p. 13).

The Gravity Model departs from Newton' Law of Gravity which states that the gravity between two objects is positively correlated with their masses and inversely related to the distance between them. This is translated into the following equation:

$$F_{ij} = G * \frac{MiMj}{D^2ij} \qquad (1)$$

Where F denotes the gravitational force between two particles and M_i and M_j represent the masses of these two objects. D expresses the distance between the two objects while G is a gravitational constant. In order to perform a regression analysis, Gravity models are expressed in natural logarithms ("ln"). Thus, the first equation (1) is transformed into the following linear equation (2) (Renert, 2008, p. 568).

$$\ln GFij = \ln Mi + \ln Mj - \ln Dij \qquad (2)$$

International Trade theorists depart from this equation and replace the gravitational forces by the trade flows or the exports from country i to country j (E*ij* in the third equation). While the variable Distance remains the same, M_i and M_j are measured by the Gross Domestic Product (GDP) of the countries i and j. b_1 and b_2 are expected to be positive whereas the sign of b_3 should be generally negative.

$$\ln Eij = \alpha + b1\ lnGDPi + b2\ lnGDPj + b3\ lnDij \qquad (3)$$

Tinbergen (1962) and Anderson (1979) were the first scholars to apply the Newton' Law of Gravity to analyse Trade flows between countries. Both authors consider transport costs measured by the geographical distance between two countries as a crucial factor to explain the intensity of trade volume between countries. The literature on the Gravity Model of Trade uses alternatively the variables GDP, GDP per capita or GDP and population to measure the masses of the economies of country i and j. Most of the empirical studies in this field show that these variables have a strong positive impact on the trade flows between two countries (for few examples, see Khan, Hag & Khan, 2013; Eita, 2008; Nguyen, B. X. 2010). Scholars using the Gravity Model of Trade have also looked at the potential of Free Trade Agreements in fostering Trade relations between countries. For instance, a study conducted by Baier and Bergstrang (2001) shows that the reductions in tariff rate and trade liberalisation have had a positive impact on the increase in world trade.

3.2. Literature review on the Gravity model of trade

As mentioned previously, the research about the determinants of pharmaceutical products is recent and remains quite scarce. Only three studies have tried to evaluate the determinants of pharmaceutical trade using the gravity model of trade, two of them concern Sweden and the other one relates to the USA trade of pharmaceuticals towards emerging countries.

In his MA thesis, Per Adolfsson used a gravity model of trade to evaluate the impact of several factors on the Swedish exports of pharmaceuticals based on the method of fixed panel data (Adolfsson, 2007). The author ran three regressions with different dependant variables for each of them. In the first regression, Per Adolfsson measures the exports of pharmaceuticals from country i to country j in Swedish krona (SEK) at time t. In the second model, the author considers the exports of pharmaceuticals in kilogrammes from country i to country j. In the third regression, the dependent variable concerns the exports of pharmaceuticals from country i to country j in SEK per unit at time t. The independent variables used in the three regressions are the following: the logarithm of the distance between the two countries in kilometres, the GDP per capita in dollars for country j at time t, the area of the country j, the population of country j at time t and some dummy variables concerning the religion, the language and the access to the ocean of the receiving country. However, one of the limits of this research is that the author is using a dependant variable which is measured in Swedish krona (SEK) whereas some of the independent variables such as the GDP and the GDP per capita of the receiving countries are measured in dollars. Moreover, one may also question the choice of the author to measure the exports of pharmaceuticals in kilos as the range of pharmaceutical products exported is very broad. Per Adolfsson's main conclusion is that the regressors "GDP per capita" have a significant positive impact on the exports of pharmaceuticals measured in SEK, kilograms and kilograms per unit (at 5% level). He shows that landlocked and remote countries are less likely to import goods from Sweden. The result of this econometric analysis also reveals that Sweden exports more pharmaceuticals towards countries that share the same religion.

The research conducted by Mats Wilkman also aims at evaluating the determinants of Swedish exports of pharmaceuticals (Wilkman, 2012). The author relies on a very similar research design than Per Adolfsson to explain the Swedish trade of pharmaceuticals.

The author ran two regressions using two different dependant variables: the exports of pharmaceuticals in SEK and the exports of pharmaceuticals in kilograms per unit. Mats Wilkman tested the same independent variables as Per Adolfsson in his research and added one regressor concerning the exchange rate between the Swedish krona and the dollars. However, the author does not include any explanatory factors related to the health sector or the protection of intellectual property rights to explain the exports of pharmaceuticals from Sweden to other countries.

At the end of his dissertation, Mats Wilkman concludes that the Swedish exports of pharmaceuticals are determined by the same factors as most other goods (p. 26). Indeed, this author shows that Sweden will export more pharmaceutical products to countries that have a higher GDP, GDP per capita and that share the same language. On the contrary, pharmaceutical exports are negatively related to the distance between two countries and changes in the exchange rate.

In her paper entitled “Determinants of the United States’ trade of pharmaceuticals”, Anne Boring (2010) uses several econometric models including a panel data with fixed effects to determine the most significant factors influencing the USA exports of pharmaceuticals towards emerging countries. One of the major innovations of Anne Boring’ paper is to include two dummy variables in the gravity equation to measure the effect of Intellectual Property Rights (IPR) on the USA exports towards emerging countries. The first one correspond to the binary variable “Free Trade Agreement” (FTA) which takes the value one when the country has signed an agreement with the United States. The variable FTA was expected to capture the effect of a strong IPR protection (p.8). Anne Boring also created a dummy variable called “TRIPS” which takes the value one when the country has implemented the agreement on Trade-Related Aspects of Intellectual Property Rights set by the World Trade Organization. When no information was available about the implementation of the TRIPS agreements, the author used the deadlines set in those documents (ibid, p. 8). However, one of the limits of this measurement is that the official date of the implementation of the TRIPS agreement might not necessarily reflect the real level of IPR in the country. Indeed, although some countries have adopted a legislation on Intellectual Property Rights in conformity with the TRIPS agreement, the regulation is not always properly enforced on the ground. Moreover, the variable Free Trade Agreement may not only capture the impact of Intellectual Property Protection but also the effects resulting from the elimination of other trade barriers between the USA and its partners.

The result of Anne Boring's analysis shows that the effect of Intellectual Property Rights is statistically insignificant to explain the USA exports of pharmaceuticals. Indeed, the variable "TRIPS" is almost always insignificant except in the reduced Ordinary Least Square (OLS) regression where the authors takes into account three basic elements of the gravity equation and the variable "Free Trade Agreement".

The last variable mentioned is insignificant in all the regressions performed. Additionally, Anne Boring found that the following factors had a statistically significant positive impact on the USA exports of pharmaceuticals: the natural logarithm of the GDP of the partner country j, the existence of a common language between the two countries, the presence of a major container port in the receiving country, out-of-pocket expenditure on health in the partner country and the adhesion of the receiving country to the "President's Emergency Plan for AIDS Relief" launched by George Bush in 2003. On the contrary, the natural logarithm of the distance between the countries (statistically significant at 1% level) and the incidence of tuberculosis per 100 000 people (statistically significant at 10% level) have a negative impact on the USA exports of pharmaceuticals towards emerging countries.

4. Methodology

The aim of this research is to test the impact of several variables on the extra EU-25 exports of pharmaceutical products. This research is based on a list of 62 countries from different regional groups over a period of 8 years (2004-2011). The diversity of the countries selected follows a recommendation done by Jeffrey A. Frankel (1997, p. 55) in his book on "Regional Trading Blocs in the World Economic System" in which he argues that *"limiting the analysis to industrialized countries is no longer convincing, even if they once were"*. The 62 countries used in this paper account for 90% of extra-EU exports of pharmaceuticals (see list in appendix 1). The panel data start in 2004, which corresponds to the enlargement of the European Union to eight Central and Eastern European countries, Cyprus and Malta.

The period selected (2004-2011) shows the factors influencing the EU-25 exports of pharmaceuticals before and after the beginning of the EU crisis which started in 2008.

Table 2: variables included in the econometric model

Type of variable	**Description of the variable**	**Expected effect on dependent variable**	**Source**
Dependent variable (y1)	Exports of pharmaceuticals in dollars from the EU to the country j	--	United Nation Comtrade database extracted via the World Integrated Trade Solution (WITS)
Independent variable (x2)	Natural logarithm of the GDP of the partner country in current dollars	Positive	World Bank database.
Independent variable (x3)	Natural logarithm of the distance in kilometers	Negative	Website : http://www.distance2villes.com/
Independent variable (x4)	Health expenditure as percentage of GDP	Positive	World Health Organisation database
Independent variable (x5)	Presence of a major port container in the receiving country (1) or not (0)	Positive	World Shipping Association's website
Independent variable (x6)	The country is landlocked (1) or has an access to the Ocean (0)	Negative	Mayer & Zignago (2011), Geodist. Centres d'Etudes Prospectives Internationales (CEPII)
Independent variable (x7)	Existence of a Free Trade Agreement between EU and the country j (1) or not (0)	Positive	European Commission, website DG Enterprise and Industry.
Independent variable (x8)	The number of people affected by tuberculosis in the country (out of 100 000 inhabitants).	Negative	World Health Organisation Database
Independent variable (x9) **[latest regression]**	The protection of Intellectual Property Rights in different countries. The index is ranked between 0 and 10	Positive	Database created from the 2007, 2008, 2009, 2010, and 2011 Reports by the Property Rights Alliances on Intellectual Property Rights Index.

The variables selected stem from the classical model of Gravity and from the review of the literature on the main determinants of pharmaceutical exports. The selection of the variables has been adapted to the case of the EU exports of pharmaceuticals. The dependant variable is the natural logarithm of the EU exports of pharmaceuticals towards the partner country expressed in current USA dollars. Following the recommendation of several scholars including James E. Anderson and Eric van Wincoop (2003, p. 170) as well as Marc Bacchetta et al (2012, p. 111), this paper uses the values of exports in nominal value rather than in real terms.

The research attempts to evaluate the explanatory power of seven independent variables on the EU exports of pharmaceuticals.

- The first variable corresponds to the natural logarithm of the Gross Domestic Product (GDP) of the partner country (country j) in current dollars. The GDP is expressed in nominal terms rather than in real terms. Indeed, according to a recent report of the World Trade Organisation (2012, p. 111): “Gravity is an expenditure function allocating nominal GDP into nominal imports; therefore inappropriate deflation probably creates biases via spurious correlations”. The GDP of the partner country measuring the economic size of the receiving country’s market, it is expected to have a positive effect on the dependent variable.
- The second independent variable is the natural logarithm of the distance between Munich and the biggest cities in the partner country measured in kilometers. Munich has been selected as it corresponds to one of the most important places in terms of pharmaceutical production within the European Union (Mandry & Mac Dougall, 2011, p. 4). The variable distance is used as a proxy for transportation costs. It is expected to have a negative influence on the dependent variable. Indeed, it is expected that the European Union should trade more with its neighboring countries.
- The third variable is the health expenditure of country j as a percentage of GDP. This is a proxy for the size of the receiving country’s health care market and should therefore have a positive effect on the dependent variable (Boring, 2010, p. 14).
- The fourth independent variable is a binary variable which measures whether the country is landlocked or has access to the sea or the ocean. Landlockedness is expected to have a negative influence on the exports of pharmaceuticals as it often implies higher transport costs (Raballand, 2002).
- The fifth explanatory variable is a dummy variable which takes the value 1 when the country possesses a major Port container and 0 when it does not. The data comes from the World shipping Council which publishes a list of the top 50 world containers. This dummy variable is used as a proxy for infrastructure quality (Boring, p. 8).

Therefore, the existence of a major Port container in the country j is expected to have a positive influence on its imports of pharmaceutical products from the EU. The fourth and fifth variables are complementary as they measure the impact of the geographical location and transport infrastructure quality on the exports of infrastructure.

We decide to include both variables as the different tests performed to check for an eventual problem of collinearity were rejected. Indeed, the Pearson correlation coefficient is smaller than 0.21 which can be interpreted as a sign of weak correlation between the variables according to Cohen (cited by Hemphill, 2003). The calculation of the Variance Inflation Factor (VIF) is also used to detect an eventual problem of multicollinearity[2]. To that end, we regressed the variable “Landlocked” on “Port Container” and obtained an R^2 of 0.0438. Based on that, we calculated the VIF which is equal to 1.045. As this number is largely inferior to 10, we can conclude that the two variables are not collinear.

Table 3: Pearson correlation coefficient.

	Portcontainer	Landlocked
Portcontainer	1.0000	
Landlocked	-0.2094	1.0000

- The sixth independent variable corresponds to the existence of a Free Trade Agreement (FTA) between the EU and the receiving country. In general, those agreements contain provisions aiming at abolishing tariff and reducing non-tariff barriers on pharmaceutical products. Therefore, Free Trade Agreements are expected to boost the EU exports of pharmaceutical products overseas.

  Some authors have pointed out that the inclusion of the variable “Free Trade agreements” is likely to introduce endogeneity issues in the gravity model in the form of “reverse causality” (Baier, S. L. Bergstrand, J. H., 2003). It means that, in some cases, Free Trade Agreements might not only be a determinant of exports but also a consequence of these exports. In other terms, major trade partners with similar GDP and which are closed to each other would tend to sign more Free Trade Agreements.

[2] The VIF equal or superior to 10 indicates a problem of multicollinearity.

One of the solutions sometimes proposed to solve this problem is to use Non-Tariff Barriers as a measure of trade costs. This can be done by assessing the amount of technical regulations and standards that may affect the trade flows between some countries. However, Anderson and Wincoop (2001) argue that these two types of non-tariff barriers can be neglected as they do not affect significantly the results. Furthermore, Novy and Chen (2011) also point out that measuring the presence or the amount of standards also raises some problems of endogeneity bias. As these authors underline it (p. 407): *"Explicit measures to capture the presence or the amount of standards and regulations by using dummy or count variables, frequency or coverage ratios but their stringency remains hard to evaluate. Implicit measures suffer from similar problems. It should be added that the possible endogeneity of standards and regulations-however measured-in explaining trade flows is another concern".* Although we are aware of the potential problems of endogeneity related to the measurements of trade costs, we still decided to include this variable "Free Trade Agreement" in the Gravity model of trade for several reasons. First of all, the results of the regression are robust and do not vary significantly with the introduction of the variable FTA. Secondly, as they are no other alternative measures of trade facilitation which would ensure better results, the variable Free Trade Agreement has been included in the model.

- The variable "Tuberculosis" represents the number of people affected by tuberculosis in the country out of 100 000 inhabitants. It is as a proxy for the country's health status which is mainly used as a control variable. We expect this explanatory variable to have a negative impact on the dependent variable. Indeed, the EU should export less pharmaceutical products to countries with low health status (Boring, 2010, p. 9).
- The last regression of this empirical chapter also aims at evaluating the effect of the respect of Intellectual Property Rights on the EU exports of pharmaceuticals. In order to measure the impact of this variable on the exports of pharmaceuticals, a database has been built by using the index on "Intellectual Property Rights" developed in four annual reports conducted by the Property Right Alliance (from 2007 to 2011).
- The Intellectual Property Rights varies between 1 and 10 and comprises four dimensions: the protection of Intellectual Property rights, the patent strength, the copyright piracy and trademark protection (Property Right Alliance, 2007, 2008, 2009, 2010, and 2011). The higher the index, the stronger the level of Intellectual Property Rights in the country. In order to calculate the IPR index, four main sources were used

by the Property Rights Alliance: the World Economic Forum's Global Competitiveness Index on Intellectual Property Rights, the Ginatre-Park Index of Patent Rights, the US Trade Representatives Watch List Report conducted by the International Intellectual Property Alliance, and the International Trademark Association' Report. In each case, the data was rescaled from 0 to 10.

A weighted average of each of those four elements was calculated to obtain the ranking of the countries for the index of Intellectual Property Rights.

Classical gravity models have generally used cross-section data to evaluate trade relations between several countries for a given year. However, panel data analyses enable us to observe the influence of some independent variables on the dependant variable across time and provide more useful information than simple cross data

Indeed, by incorporating both cross-sectional and time series dimensions, panel data deliver more accurate inference of the variables tested and control for the effect of missing or unobserved variables. In light of those advantages, this paper will rely on the method of static panel data[3]. Using our dataset, we estimate the following gravity equation:

$$lnexport_{\mathrm{ijt}} = \beta_1 lnGDP_j + \beta_2\, lndist_{ij} + \beta_3\, healthspending_{jt} + \beta_4\, landlocked_j + \beta_5\, FTA_{ijt} + \beta_6\, Tuberculosis_{jt} + \beta_7\, Portcontainer_j + \alpha_n\, Country_n + \omega_n\, Year_n + \mathrm{U_{ijt}}$$

Where

$\mathrm{lnexport_{ijt}}$= natural logarithm of the EU exports of pharmaceuticals (country i) towards the partner country (country j) expressed in current dollars,

$\mathrm{lnGDP_j}$ = natural logarithm of the GDP of country j in current dollars,

$\mathrm{lndist_{ij}}$ = natural logarithm of the distance between country i and country j in kilometers,

$\mathrm{healthspending_j}$ = health expenditure of country j as percentage of its GDP,

$\mathrm{landlocked_j}$= indicates whether the country j is landlocked (1) or has an access to the sea (0),

$\mathrm{FTA_{ij}}$ = shows the existence of a Free Trade Agreement between country i and j (1) or not (0),

$\mathrm{Tuberculosis_j}$ = number of people affected by tuberculosis in the country j out of 100 000 inhabitants

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[3] The impact of Intellectual Property Rights on EU exports of Pharmaceuticals will be analyzed by conducting an Ordinary Least Square Regression. This is due to the fact that the data on IPR is available only from 2007 to 2011.

Portcontainer_j=indicates the existence of a major port container (1) in the receiving country.

Country_n = dummy variable for the countries included in the model[4].

Year_n= dummy variable for the years contained in the model[5].

Uij = error term,

t = time period

Bs = parameters.

α_n = coefficients corresponding to the binary regressors country

ω_n = coefficients for the binary time regressors[6]

We expect the signs of β_1, β_3, β_5, β_7 to be positive while β_2, β_4, β_6 should be negative.

5. Econometric analysis

5.1. First estimation of the model

Table 4: Result of the first regression

Variables	**Model 1**	
ln GDP (dollars)	0.620***	(0.00)
Free Trade Agreement	0.0880	(0.12)
Ln distance (kms)	-0.320	(0.13)
Tuberculosis	-0.000126	(0.82)
Landlocked	-1.086*	(0.04)
Health spending	0.0609***	(0.00)
Port container	0.943	(0.07)
Constant	5.301**	(0.01)
Observations	496	

*P-values in parentheses: * p<0.05, ** p<0.01, *** p<0.001*

[4] In order not to fall into the dummy trap, we included n-1 countries in the model (that is to say 61 countries).

[5] To avoid the dummy trap, we exclude the year 2004 of our model.

[6]As we are dealing with binary variables, we have t-1 time periods in the equation.

The first model was estimated by using the method of panel data with fixed and time effects. Subsequently, we regressed the logarithm of the EU exports of pharmaceuticals on the logarithm of the GDP of country j, the logarithm of the distance and the variables tuberculosis, healthspending, landlocked, FTA, Portcontainer, i.years[7] and i.country[8].

After running this regression, the F-test was carried out to evaluate the joint nullity of all the explanatory variables of the model. The test led to a strong rejection of the null hypothesis indicating that the fixed effects are highly significant at 1% level. The command testparm was also used to verify whether it was necessary to include the binary variables "Country_n" and "Year_n" in our analysis. Both tests led to a strong rejection of the null hypothesis which indicates that the two aforementioned variables were statistically jointly significant. The other explanatory factors which were found to be statistically significant at 5% level were the variable "healthspending", the logarithm of the GDP of the receiving country and the binary variable "landlocked".

The variable "Port container" is statistically significant at 10% level. However, the explanatory factors "Free Trade Agreement", "ln distance" and "Tuberculosis" are not statistically different from zero even at a 10% level.

Table 5: Results of the Breusch-Pagan and Ramsey reset test

Results of the Ramsey RESET test
Ho: model has no omitted variables
F(3, 419) = 5.00
Prob > F = 0.0020

Breusch-Pagan / Cook-Weisberg test for heteroskedasticity
Ho: Constant variance
chi2(1) = 15.48
Prob > chi2 = 0.0001

Several misspecification tests were also carried out to control for functional form misspecification and heteroskedasticity. Given the size of the sample (62 countries over 8 years), one can assume that the variables are normally distributed.

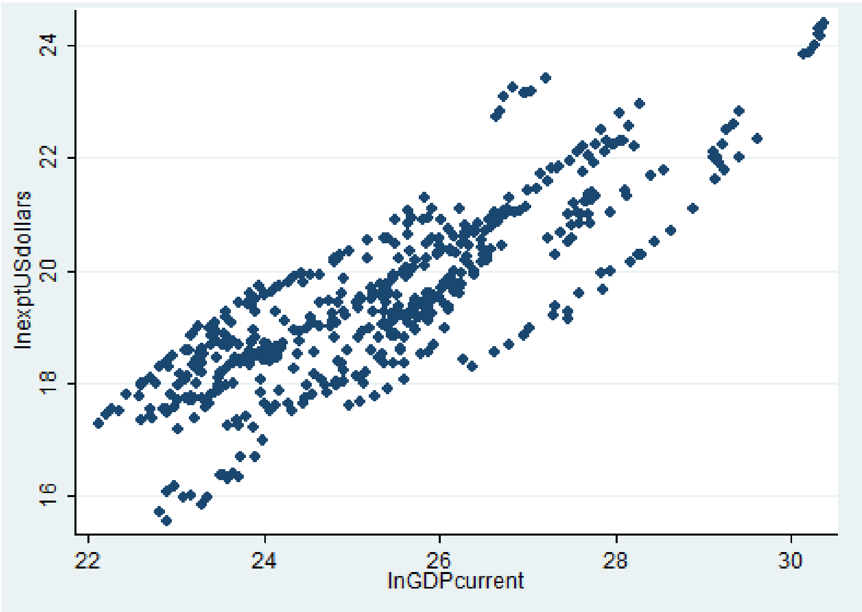
[7] i.years is a dummy variable created for each year.
[8] i.country is a dummy variable created for each partner country j.

However, the result of the Breusch-Pagan test led to a strong rejection of the assumption of homoscedasticity at 1% level (Table 3). The Ramsey RESET test also led to a rejection of the null hypothesis at 5% level indicating a problem of functional form misspecification (Table 4). This problem can occur when the regression is nonlinear in the parameters.

5.2. Redefinition of the model

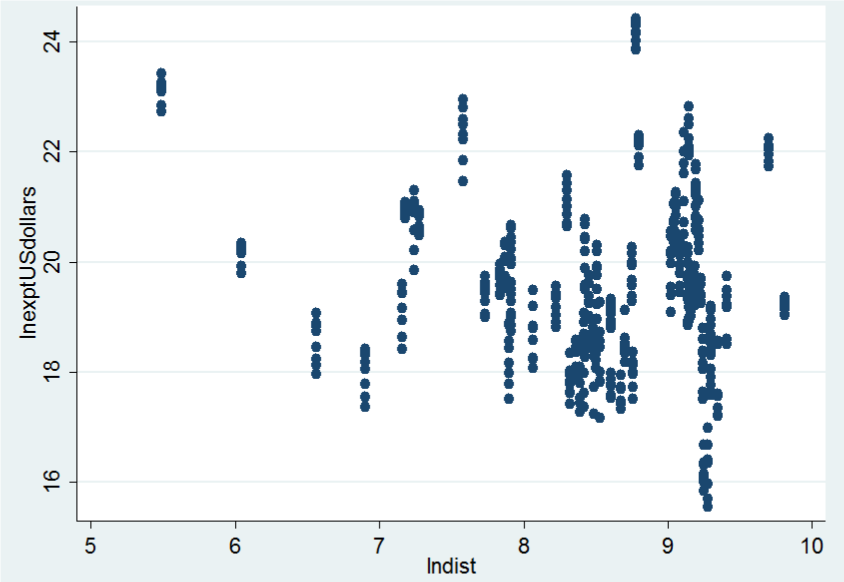
In light of the results of the Ramsey Reset test, we tried to determine which independent variables could have a non-linear relation with the dependent variable. First of all, we draw a scatterplot between the natural logarithm of the GDP of the receiving country in current dollars and the natural logarithm of the EU exports of pharmaceuticals in current dollars. The following scatterplot (Graph 1) shows that the relation between these two variables is quadratic rather than linear.

Graph 1: Relation between the natural logarithm of the GDP of the country j and the natural logarithm of the EU exports of pharmaceuticals in current dollars.



Graph 2 also reveals that the relation between the natural logarithm of the distance in kilometers and the natural logarithm of the EU exports of pharmaceuticals in current dollars is not linear.

Graph 2: Relation between the natural logarithm of the distance in kilometers and the natural logarithm of the exports in current dollars.



In light of those results, we therefore introduced two new variables in the model namely the square of the natural logarithm of distance in kilometers (ln distance²) and the square of the natural logarithm of GDP in current dollars (ln GDP²) in order to avoid the problem of functional form misspecification. Moreover, following the result of the Breusch-Pagan test, we robustified the regression against heteroskedasticity.

Therefore, the model is now redefined as follows:

$$lnexport_{\mathrm{ijt}} = \beta_1 lnGDP_{jt} + \beta_2 (lnGDP)^2_{jt} + \beta_3 \, lndistance_{ij} + \beta_3 \, (lndistance)^2_{ij} + \beta_3 \, healthspending_{jt} + \beta_4 \, landlocked_j + \beta_5 \, FTA_{ijt} + \beta_6 \, Tuberculosis_{jt} + \beta_7 \, Portcontainer_j + \alpha_n \, Country_n + \omega_n \, Year_n + U_{\mathrm{ijt}}$$

Table 6 presents the result of this regression obtained in STATA[9]. The results of this regression are quite different from the former model. Indeed, all the explanatory variables of this model are statistically significant at 5% level except the variables “tuberculosis” and “landlocked”. The Ramset RESET test fails to reject the null hypothesis at 5% level. Since this model does not suffer from functional form misspecification, this regression should be preferred to the previous one on statistically ground.

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[9] The table only displays the coefficient of the variables of interest in our model.

Table 6: Results of the second regression

Variables	Model 2	
ln GDP (dollars)	-1.129*	(0.03)
ln GDP² (dollars)	0.0344***	(0.00)
Free Trade Agreement	0.122*	(0.04)
Ln distance (kms)	-12.42***	(0.00)
ln distance² (kms)	0.711***	(0.00)
Tuberculosis	-0.00104	(0.20)
Landlocked	0.526	(0.31)
Health spending	0.0510***	(0.00)
Port container	2.812***	(0.00)
Constant	77.12***	(0.00)
Observations	496	

*P-values in parentheses: * p<0.05, ** p<0.01, *** p<0.001*

Table 7: Result of the Ramsey test

Ho: model has no omitted variables	
F(3, 417) =	0.87
Prob > F =	0.4577

The coefficient of the variables "FTA", "Health spending" and "Portcontainer" have the expected signs. Indeed, the existence of a Free Trade Agreement is expected to increase EU exports by 12.2% holding other factors constant. Moreover, a one percent point increase in health expenditure (as a percentage of GDP) will increase the exports of pharmaceuticals in dollars by 5.1%. If a country possesses a major Port container, it is expected to import 281% more pharmaceutical products from the European Union than if it doesn't.

In order to better interpret the sign of the coefficients of the variables "ln distance" and "ln GDP", we used the command margin in STATA. This enables us to obtain the partial effect of the logarithm of distance and the logarithm of the GDP of the partner country on the dependent variable at its mean value. Indeed, the function margin calculates the derivative of the natural logarithm of the EU exports of pharmaceuticals in current dollars with respect to the variable "ln GDP" at its mean value. Table 8 displays the result obtained in STATA. It shows that the variables "ln GDP" and "ln distance" are statistically significant at 1% level. A 1% increase in the GDP of the receiving country is expected to result in a 0.62% increase in the EU exports of pharmaceuticals. A 1% in the distance between the EU and the country j measured in kilometers is expected to result in a decrease of 0.37% in the EU exports of pharmaceuticals towards this state.

Table 8: Partial effect of "ln GDP" and "lndist" on the dependent variable

Variables	dy/dx	P>z
Ln GDP (dollars)	.6194133	0.000
Ln distance (kms)	-.3683497	0.001

5.3. Regression with clustered data

We now consider the possibility that the observations for each country over several years are not independent but correlated. In order to control for this problem, we use the cluster option on country. Table 9 displays the main results of this model.

Table 9: results of the third regression

Variables	Model 3	
ln GDP (dollars)	-1.129	(0.21)
ln GDP² (dollars)	0.0344	(0.06)
Free Trade Agreement	0.122	(0.10)
Ln distance (kms)	-12.42***	(0.00)
ln distance² (kms)	0.711***	(0.00)
Tuberculosis	-0.00104	(0.46)
Landlocked	0.526	(0.40)
Health spending	0.0510*	(0.01)
Port container	2.812***	(0.00)
Constant	77.12***	(0.00)
Observations	496	

*P-values in parentheses: * p<0.05, ** p<0.01, *** p<0.001*

The result of this regression is different from the previous one. Indeed, the variables “ln GDP” and “Free Trade Agreement” are not statistically significant. Moreover, the variable “ln GDP²” is only significant at a 10% level.

As in the previous regression, the variables “Health spending”, “Port container”, “ln distance”, “ln distance²” are statistically significant at 5% level. The command margin was performed to evaluate the marginal effect of the distance and the GDP of the country j on the dependent variable.

Table 10: Partial effects of “ln GDP” and “ln distance” on the dependent variable

	dy/dx	P>z
Ln GDP (dollars)	.6194133	0.000
Ln distance (kms)	-.3683497	0.000

Table 10 indicates that the effect of the logarithm of GDP on the dependent variable is statistically significant at 0.1% level. The coefficient reveals that the relation between the GDP of the receiving country and the EU exports of pharmaceutical products measured in dollars is positive, as we expected. The result doesn’t differ from the previous regression. Indeed, a 1% increase in the GDP of the receiving country is expected to increase the EU exports of pharmaceuticals towards this country by 0.62%. The effect of the natural logarithm of distance on the EU exports of pharmaceuticals is also statistically significant at 1% level. The negative sign of the coefficient indicates that the relation between those two variables is negative. Therefore, a 1% increase in the distance between the EU and its partner country is expected to decrease the EU exports of pharmaceuticals by 0.37 %.

5.4. Regression with Intellectual Property Rights

In order to measure the impact of Intellectual Property Rights on the exports of Pharmaceuticals from the EU, we created a database using the Reports on Intellectual Property Rights Index written by the Property Right Alliance. Since these reports only started in 2007, the data on intellectual property was only available from 2007 until 2011.

Given the fact that we could only test the effect of the variable “Intellectual Property Rights” over a period of three years, we conducted a simple regression analysis using the method of Ordinary Least Square. The result is summarised in the following table:

Table 11: results of the fourth regression with IPR

Variables	**Model 4**	
ln GDP (dollars)	0.642***	(0.00)
Free Trade Agreement	-0.0287	(0.81)
Ln distance (kms)	-0.610***	(0.00)
Tuberculosis	0.0000646	(0.70)
Landlocked	-0.138	(0.62)
Health spending	0.100***	(0.00)
Port container	0.434***	(0.00)
Intellectual Property Rights	0.141***	(0.00)
Constant	7.061***	(0.00)
Observations	161	

As we can see from Table 11, the variable “Intellectual Property Right (IPR)” has a statistically significant impact on the EU exports of pharmaceuticals at 1% level. This means that a one unit increase in the rating of a country on Intellectual Property Right is expected to increase the EU exports of pharmaceuticals by 14.1% holding other factors constant.

5.5. Discussion of the results

The first regression of our model indicates that the variables “Healthspending”, the logarithm of the GDP, the dummy variable “landlocked” have a statistically significant impact on the EU exports of pharmaceuticals at 5% level. The variable “Portcontainer” was also statistically significant at 10% level. However, since this regression didn’t pass the test of functional form misspecification, we added the square of the variable “ln GDP” and the square of “ln distance” into our initial equation. We also robustified our model in order to avoid the problem of heteroskedasticity detected by the Breusch Pagan test.

Table 12: Summary of the results of the different regressions

Variables	Model 1		Model 2		Model 3		Model 4	
ln GDP (dollars)	0.620***	(0.00)	-1.129*	(0.03)	-1.129	(0.21)	0.642***	(0.00)
FTA	0.0880	(0.12)	0.122*	(0.04)	0.122	(0.10)	-0.0287	(0.81)
Ln distance (km)	-0.320	(0.13)	-12.42***	(0.00)	-12.42***	(0.00)	-0.610***	(0.00)
Tuberculosis	-0.000126	(0.82)	-0.00104	(0.20)	-0.00104	(0.46)	0.0000646	(0.70)
Landlocked	-1.086*	(0.04)	0.526	(0.31)	0.526	(0.40)	-0.138	(0.62)
Health spending	0.0609***	(0.00)	0.0510***	(0.00)	0.0510*	(0.01)	0.100***	(0.00)
Port container	0.943	(0.07)	2.812***	(0.00)	2.812***	(0.00)	0.434***	(0.00)
ln GDP² (dollars)			0.0344***	(0.00)	0.0344	(0.06)		
ln distance² kms)			0.711***	(0.00)	0.711***	(0.00)		
IPR							0.141***	(0.00)
Observations	496		496		496		161	

The second regression shows that all explanatory variables of this model are statistically significant at 5% level except the variables “tuberculosis” and “landlocked”. These results are similar to a certain extent to the one obtained by Per Adolfsson, Mats Wilkman and Anne Boring. Indeed, in their respective research, those authors showed that the Swedish and USA exports of pharmaceuticals depend positively on the economic size of the receiving country, and negatively on the distance between the country i and j. Contrary to Per Adolfsson’s results concerning the case of Sweden, this paper shows that the exports of EU pharmaceutical products are not influenced by access to the sea of the partner country.

However, the presence of a major container port in the receiving country has a significant positive effect on the EU exports of pharmaceuticals towards those countries. This conclusion is similar to the one reached by Anne Boring. Indeed, she showed that countries with big container ports are more likely to import pharmaceutical products from the USA. However, contrary to this researcher, we found that the variable “tuberculosis” did not have a statistically significant impact on the EU exports of pharmaceuticals even at 10% level whereas the total health expenditure as a percentage of GDP had a very strong positive effect on the dependent variable. These results can be explained by the different research designs of our respective researches.

While Anne Boring's research focuses on the USA trade with emerging countries, this article examines the determinants of EU exports towards the rest of the world. This could explain why the variable "Tuberculosis" is statistically significant in her research and not in this one. However, the significance of the variable "healthspending" in this article suggests that the bigger the size of the health sector of the partner country, the more the EU will have opportunities to export to those countries.

A third regression was run to control for an eventual problem of correlation between the observations for each country over several years. The result of this regression does not differ so much from the previous one. The biggest difference between the second and third regression lies in the fact that the variable Free Trade Agreement is not statistically significant anymore.

Finally, the fourth regression reveals the strong positive effect of the protection of Intellectual Property Rights on the EU exports of pharmaceuticals. This result strongly differs from the one obtained by Anne Boring in 2010 for the case of the USA trade of pharmaceuticals where the dummy variables used as a proxy for Intellectual Property Protection did not appear to have a statistically significant impact on the dependent variable. The last regression performed confirms the statistical significance at 1% level of the GDP of the receiving country, the distance, the presence of a major port container and the level of health spending in the receiving country on the EU exports of pharmaceuticals. However, the variable Free Trade Agreement does not appear to be statistically significant even at 10% level.

Overall, one can therefore argue that the different regressions performed confirm our main hypotheses. The protection of Intellectual Property, the GDP of the partner country, the importance of the health sector of the receiving country and the presence of a major port container in the country j have a positive impact on the EU exports of pharmaceuticals overseas. On the contrary, as we expected, the transport costs measured by the distance between the EU and the receiving country have a negative effect on the extra EU-25 exports of pharmaceuticals. It is difficult, however, to draw any definitive conclusions regarding the impact of Free Trade Agreements on the EU exports of pharmaceuticals since the last regressions of this econometric analysis yield different results.

6. Conclusions

The EU pharmaceutical industry is an important source of growth and competitiveness for the European Economy. However, despite the importance of this sector for the future of the European Union, few academics have analyzed the European pharmaceutical industry from a trade-related perceptive. Most of the research on the European pharmaceutical industry generally focuses on its impact on the health sector or on the rules to maintain competition in the industry. This lack of research on the EU exports of pharmaceuticals is all the more surprising in a context of economic crisis where trade has a major role to play to boost EU competitiveness and growth. The aim of this paper was to fill this literature gap by enhancing our knowledge of the drivers and obstacles to the extra-EU exports of pharmaceuticals.

The first section of this paper summarises the main findings of some official reports regarding the main barriers for the EU exports of pharmaceuticals. This literature review sheds light on the importance of tariffs and non-tariff barriers as well as on the level of intellectual Property Rights on the EU exports of pharmaceuticals. This paper seeks to complete this qualitative analysis by providing an econometric assessment of the main determinants of the EU exports of pharmaceuticals. Based on the Gravity model of Trade, this paper formulated various hypotheses concerning the determinants of the EU exports of pharmaceuticals.

This research has revealed that several variables have a significant impact on the EU exports of pharmaceuticals. We found that the economic size of the partner country has a positive effect on the exports of pharmaceuticals, while the distance between the EU and the importing countries has a negative impact on the trade of pharmaceuticals. This paper also shows the importance of the quality of infrastructure on the trade of pharmaceuticals. Indeed, the different regressions highlight that countries with large container ports tend to import more pharmaceutical products from the EU. The EU exports of pharmaceuticals were also influenced by the size of the healthcare sector of the partner country. Thus, the EU is likely to export more pharmaceutical products to countries that have a higher level of healthcare expenditure as a percentage of GDP. Finally, this paper shows that the level of Intellectual Property Rights of the receiving country has a positive effect on the EU exports of pharmaceuticals. Indeed, the higher the protection of Intellectual Property in one country, the more the EU will be able to export pharmaceutical products towards this state. However, access to the sea of the receiving countries did not have a statistically significant impact on the dependent variable. Moreover, it was difficult to draw any definitive conclusions regarding the impact of Free Trade Agreements on the EU exports of pharmaceuticals since our regressions yield different results. Based on the gravity model of trade, this paper sheds light on the key drivers to the EU exports of pharmaceuticals. However, further analysis could be carried out to in the future to quantify the impact of tariff and non-tariff barriers on the exports of pharmaceuticals. It could also be interesting to adopt a comparative approach to examine to what extent the factors driving the exports of pharmaceuticals are the same in different countries.

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Appendix

List of countries included in the sample

Russia
Switzerland
Australia
Ukraine
Algeria
Saudi Arabia
South Africa
Norway
United Arab Emirates
Croatia
Vietnam
Israel
Mexico
Kazakhstan
Egypt
Morocco
Jordan
Côte d'Ivoire
Lebanon
Nigeria
Belarus
Senegal
Bosnia and Herzegovina
Singapore
Iraq
New Zealand
Uzbekistan
Kuwait
Ghana
Angola
Sudan

Cameroon
Pakistan
Colombia
Albania
Panama
Benin
Georgia
Congo
Kenya
Gabon
Japan
Indonesia
South Korea
Malaysia
Philippine
Thailand
China
Canada
United states
Brazil
Chile
Colombia
Ecuador
Peru
Venezuela
Bolivia
Paraguay
Uruguay
India
Ethiopia
Qatar