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INTELLECTUAL PROPERTY OFFICE

THE ECONOMIC COST OF IPR INFRINGEMENT IN THE PHARMACEUTICAL INDUSTRY

Quantification of infringement in Manufacture of pharmaceutical preparations (NACE 21.20)

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PROJECT TEAM

Nathan Wajsman, Chief Economist
Carolina Arias Burgos, Economist
Christopher Davies, Economist

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EXECUTIVE SUMMARY

THE ECONOMIC COST OF IPR INFRINGEMENT IN THE PHARMACEUTICAL INDUSTRY

The European Observatory on infringements of Intellectual Property Rights (the Observatory) was created to improve the understanding of the role of Intellectual Property and of the negative consequences of Intellectual Property Rights (IPR) infringements.

In a study carried out in collaboration with the European Patent Office[1], the European Union Intellectual Property Office (EUIPO)[2], acting through the Observatory, estimated that approximately 39% of total economic activity and 26% of all employment in the EU is directly generated by IPR-intensive industries, with a further 9% of jobs in the EU arising from purchases of goods and services from other industries by IPR-intensive industries.

Another study[3] compared economic performance of European companies that own IPRs with those that do not, finding that IPRs owners' revenue per employee is 28% higher on average than for non-owners, with a particularly strong effect for Small and Medium-Sized Enterprises (SMEs). Although only 9% of SMEs own registered IPRs, those that do have almost 32% more revenue per employee than those that do not.

Perceptions and behaviours of European citizens regarding Intellectual Property and counterfeiting and piracy[4] were also assessed as part of an EU-wide survey. This survey revealed that although citizens recognise the value of IP in principle, they also tend to justify infringements at individual level in certain cases.

The Observatory is seeking to complete the picture by assessing the economic impact of counterfeiting and piracy.

This exercise is challenging from a methodological point of view, as it attempts to shed light on a phenomenon that by its very nature is not directly observable. To pave the way towards quantification of the scope, scale and impact of IPR infringements in the European Union, as identified in its mandate, the Observatory has developed a step by step approach to evaluate the negative impact of counterfeiting and its consequences for legitimate businesses, governments and consumers, and ultimately society as a whole.

Several IPR intensive industries whose products are known or thought to be subject to counterfeiting have been selected. Previous studies have examined the following sectors: cosmetics & personal care; clothing, footwear and accessories; sports goods; toys & games; jewellery & watches; handbags & luggage; recorded music, and spirits & wine. This report presents the results of the ninth sectorial study, covering the production of pharmaceutical preparations[5]. The EPO/OHIM (2013) study revealed that this industry is intensive in the use of trade marks and patents.

1 - "Intellectual Property Rights intensive industries; contribution to economic performance and employment in the European Union", OHIM/EPO, September 2013.

2 - Until 23 March 2016, the name of the Office was Office for Harmonization in the Internal Market (OHIM). The name was changed to EUIPO as part of the trade mark reform legislation which came into force on that date.

3 - "Intellectual Property Rights and firm performance in Europe: an economic analysis", June 2015.

4 - "European citizens and intellectual property: perception, awareness and behaviour", November 2013

5 - The sector analysed here comprises the four digit NACE code: 21.20 "Manufacture of pharmaceuticals preparations" as well as the NACE code 46.46 "Wholesale of pharmaceutical goods". NACE is the official classification of economic activity used by Eurostat, the statistical office of the EU.

It is estimated that the legitimate industry loses approximately **€10 billion** of revenue annually due to the presence of counterfeit medicines[6] in the EU marketplace, corresponding to **4.4% of the sector's sales.**

These lost sales translate into direct employment losses of approximately 38,000 jobs. This figure does not take account of the effect of imports, since in those cases the associated employment impacts occur outside of the EU. Nor does it include losses suffered by EU producers as a result of counterfeiting in non-EU markets. Estimated employment losses in the EU therefore relate to goods produced and consumed within the EU.

If the knock-on effects on other industries and on government revenue are added, when both the direct and indirect effects are considered, counterfeiting in this sector causes approximately €17 billion of lost sales to the EU economy, which in turns leads to employment losses of about 91,000 jobs and a loss of €1.7 billion in government revenues.

It is important to note that the impact of counterfeit medicines refers to the manufacturing and wholesale trade stages and so does not include retail trade[7]. For that reason, the absolute numbers in this report cannot be directly compared to those previously presented for other sectors.

1. INTRODUCTION

THE ECONOMIC COST OF IPR INFRINGEMENT IN THE PHARMACEUTICAL INDUSTRY

A major problem which has hindered the effective enforcement of Intellectual Property Rights (IPR) in the EU is related to a lack of knowledge in relation to the precise scope, scale and impact of IPR infringements. Many attempts to quantify the scale of counterfeiting and its consequences for businesses, consumers and society as a whole have suffered from the absence of a consensual and consistent methodology for collecting and analysing data on counterfeiting and piracy across various sectors. Different approaches have been used, such as surveys, mystery shopping or monitoring of online activities, making it all the more difficult to aggregate results for the whole economy. The very nature of the phenomenon under investigation makes it extremely challenging to quantify reliably, as obtaining comprehensive data for a hidden and secretive activity is by necessity difficult.

These challenges have in turn hindered the tasks of those involved in enforcing IP rights and in charge of establishing precise priorities, programmes and targets for enforcement, as they limit the possibilities to design more focused policies as well as evidence-based public awareness campaigns.

To help overcome these challenges while taking fully into account of methodological constraints, the Observatory developed a specific approach that has so far been applied to the Cosmetics and Personal Care; Clothing, Footwear and Accessories; Sports Goods; Games and Toys; Jewellery and Watches; Handbags and Luggage; Recorded Music; and Wine and Spirits sectors.

In the present report the Observatory focuses its attention on the Pharmaceutical Industry including manufacturing as well as wholesale trade. The industry, as defined by Eurostat, includes the following NACE classes:

2120 Manufacture of pharmaceutical preparations.

This class includes:

- Manufacture of medicaments: antisera and other blood fractions, vaccines, diverse medicaments including homeopathic preparations;
- Manufacture of chemical contraceptive products for external use and hormonal contraceptive medicaments;
- Manufacture of medical diagnostic preparations, including pregnancy tests;
- Manufacture of radioactive in-vivo diagnostic substances;
- Manufacture of biotech pharmaceuticals.

This class excludes, among others:

▌ Manufacture of herbs infusion (mint, vervain, chamomile, etc);
▌ Manufacture of dental fillings and dental cement;
▌ Manufacture of bone reconstruction cements;
▌ Manufacture of surgical drapes;

4646 Wholesale of pharmaceutical and medical goods; therefore, sales figures in this report are based on wholesale prices.

This study aims to estimate the scale of the two major economic impacts of counterfeiting which cover the direct and indirect costs to industry and the wider costs to government and society.

1) DIRECT COSTS TO INDUSTRY

The costs to industry consist mainly of lost sales due to counterfeiting. Estimation of lost sales is therefore a necessary first step, both because it constitutes a major economic consequence in itself and because it drives other consequences, for example the loss of public fiscal revenue.

The methodology builds on an adaptation of a methodology developed for the European Commission[8] so that it can be used on a sectorial level rather than on a firm level which proved very difficult to apply in practice.

Variations in a sector's sales are analysed using statistical techniques which allow the researcher to relate them to economic and social factors and thereby estimate the amount of sales lost by rights holders due to counterfeiting.

Loss of sales also leads to loss of employment in the affected sectors, which can be derived from European statistical data on employment for the sectors in question.

2) INDIRECT EFFECTS OF COUNTERFEITING

In addition to the direct loss of sales in the identified sector, there are also impacts on other sectors of the EU economy. These indirect effects are a result of the fact that the different sectors of the economy buy goods and services from each other for use in their production processes. If one sector's sales are reduced because of counterfeiting, then this sector will also

8 - RAND (2012): *Measuring IPR infringements in the internal market.* Report prepared for the European Commission. RAND proposed to analyse ex-post the forecast errors on the level of individual companies, using company-specific explanatory variables. However, attempts at implementing the methodology in this manner were not successful, mainly due to the fact that most companies are not able or willing to provide the required data on past budgeted and actual sales revenues. Therefore, the methodology has been modified to allow its use on sector-level data which can be obtained from public sources.

buy fewer goods and services from its suppliers, causing sales declines and corresponding employment effects in other sectors.

3) IMPACTS ON PUBLIC FINANCES

Since the activity in question is illegal, it is likely that those engaged in manufacture of counterfeit goods do not pay taxes on the resulting revenues and incomes. Therefore, an additional impact of counterfeiting is the resulting losses of tax revenue by government, specifically income taxes and social contributions or corporate taxes.

In order to quantify these costs, several relationships are estimated using statistical techniques. The methodology is fully explained in the Appendices and is briefly outlined below.

Step 1: Estimation of lost sales due to counterfeiting

Predicted sales of relevant sectors are generated and compared with actual sales in each country, as reported in official statistics. The difference can then be partly explained by socio-economic factors such as GDP growth or per capita income. In addition, factors related to counterfeiting are considered, such as behaviour of consumers[9], and the characteristics of a country's markets and its legal and regulatory environments[10]. The difference between forecast and actual sales is analysed in order to extract the effect of counterfeit consumption on legitimate sales.

Step 2: Translation of lost sales into lost jobs and lost public revenue

Since the legitimate industry sells less than it would have sold in the absence of counterfeiting, it also employs fewer workers. Data from Eurostat on employment in this sector is used to estimate the employment lost related to the reduction of legitimate business as a result of lost sales due to counterfeiting.

In addition to the direct loss of sales in the sector being analysed, there are also indirect impacts elsewhere in the economy, as this sector will also buy fewer goods and services from its suppliers, causing sales declines and corresponding employment effects in other sectors.

Furthermore, the reduced economic activity in the private sector has an impact on government revenue, essentially tax revenue such as household income tax and tax on company profits, but also social security contributions.

9 - Results from the IP Perception Study published by the EUIPO in November 2013 are used, such as the propensity of EU citizens to buy counterfeit goods as a result of being misled.

10 - Worldwide Governance Indicator of Regulatory Quality from the World Bank is used for the pharmaceutical sector analysed in this report.

It should be noted that the indirect effect of sales lost due to counterfeiting only includes losses in sectors that provide inputs to the manufacture and distribution of legal products in the EU. Possible effects of inputs provided for production of illicit goods that could be manufactured inside or outside the EU, are ignored in this study. In other words, the indirect effect calculated is a gross effect that does not take into account the long-term effect of sales displacement from legal to illegal producers. The net employment effect could therefore be smaller than the gross effect calculated here[11].

Similarly, while illicit activities do not generate the same levels of tax revenue as legal activities, to the extent that sales of counterfeits happen in the legitimate sales channels, some direct and indirect taxes are paid, and so the net reduction in government revenue may be smaller than the gross effect calculated here[12]. Unfortunately, data currently available do not allow for calculation of these net effects with any degree of accuracy.

This study, as is the case with the previous sectorial studies, focuses on the economic impact of the presence of counterfeit medicines in the EU marketplace. However, due to the special nature of pharmaceutical preparations, it is important to point out the very significant health issues associated with fake medicines. Death or permanent disabilities can result when such products are consumed by the patient, either because they do not contain the active substance they are supposed to contain, or because the dose of the substance is inadequate, irregular or just plainly wrong. In some cases the counterfeit products contain other dangerous substances and can therefore be directly life threatening. Besides the human suffering they entail, these effects also have economic consequences for society and notably on the health systems of EU Member States. Such economic consequences can unfortunately not be taken into account in the present study due to the difficulty of quantifying them, but they should be kept in mind when considering the phenomenon of counterfeit pharmaceutical products.

The next section presents the main findings of the study.

2. IMPACT OF COUNTERFEITING IN THE PHARMACEUTICAL INDUSTRY

THE ECONOMIC COST OF IPR INFRINGEMENT IN THE PHARMACEUTICAL INDUSTRY

The starting point of this analysis is the estimation of consumption of medicines by Member State based on official data from Eurostat on production, wholesale margins and intra- and extra-EU trade. As mentioned above, retail trade is not included in the analysis; therefore, consumption of pharmaceuticals analysed in this report is stated at wholesale prices and thus does not include the trade margins generated by retailers.

The Pharmaceutical industry in the EU

During 2013, EU production of pharmaceuticals amounted to €180 billion and wholesale margins to €104 billion, for a total of €284 billion at wholesale prices. EU exports to third countries were worth €100 billion, and imports from third countries amounted to €46 billion, resulting in a positive trade balance of €54 billion, and leaving nearly €230 billion (at wholesale prices) or €450 per capita, for consumption of medicines in the internal market.

In the same year, there were about 1.1 million people employed in the pharmaceutical industry across the EU, with approximately half a million employed in manufacturing and 600 thousand in wholesale trade.

In previous sectorial studies the different products analysed were directly consumed by private households. However, in the case of medicines, the EU Input-Output Table[13] shows that they are used as intermediate goods as well as for final demand (which includes final consumption expenditure by households and governments as well as exports and changes in inventories). The use of the pharmaceutical industry's products is shown in the figure below.

13 - EU Input-Output Tables are only available at division level so we refer to NACE 21 'Basic pharmaceutical products and pharmaceutical preparations'. Following SBS, class 2120 production represents 86% of division 21 in the EU28 in 2013.

Pie chart legend:
- PHARMA INDUSTRY — 10%
- HEALTH SERVICES — 17%
- OTHER INDUSTRIES — 5%
- HOUSEHOLDS — 17%
- GOVERNMENT — 23%
- OTHER FINAL USES — 28%
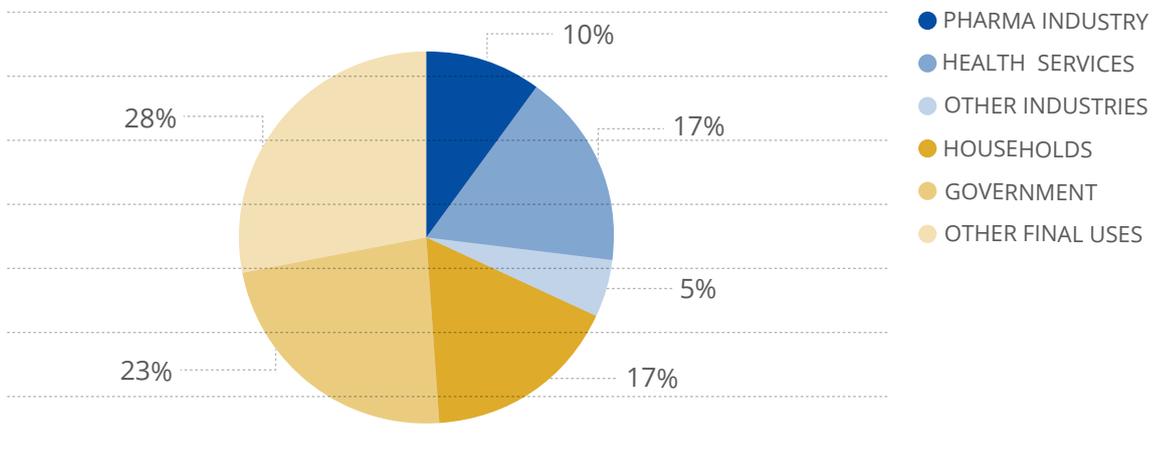
The use of pharmaceutical products for intermediate consumption is concentrated in health services and the pharmaceutical industry itself and accounts for 27% of total value of output at producer prices (without trade margins or VAT). The final uses of medicines include final consumption (40%) that can be paid by governments (23%) and households (17%) and also other final uses, including exports to third countries and changes in inventories. While this is the structure of the use of medicines on the level of the EU as a whole, it should be noted that there are significant differences among Member States in this regard.

The biggest producer of pharmaceuticals in the EU is Germany (€41 billion), followed by Ireland (€26 billion), France (€25 billion) and Italy (€20 billion). These countries are also the major exporters with a trade balance of €25 billion in the case of Germany and €14 billion in Ireland, and total net exports of 28 EU countries to third countries of more than €54 billion.

The EU pharmaceutical industry consists of more than 40,000 enterprises of which 3,000 are manufacturers and the rest are wholesalers. The average size of firms differs significantly between the two groups, with manufacturers at 150 and wholesalers at 15 workers per firm, respectively.

CASE 1: COUNTERFEIT CANCER MEDICINES IN GERMANY

The Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM) issued an appeal to German pharmacies in June 2014, urging them to closely examine their stocks of parallel-imported Sutent medication. Sutent (active ingredient: Sunitinib) is a medication used for treatment of certain cancers of the intestines, kidneys and pancreas. It is manufactured by Pfizer, a U.S.-based pharmaceutical company.

Orifarm is the largest supplier of parallel imported medicine in Europe. The company imports original pharmaceuticals from EU Member States at lower price levels and is then able to sell them at lower prices than the original manufacturers in Member States where prices are higher.

A pharmacy in Hamburg was contacted by a patient in May 2014. The patient had purchased a package of Sutent from that pharmacy, but brought it back because it seemed to him that it did not contain the genuine medication. After consultations between Orifarm, which had supplied the medication, and the authorities, it was decided to recall 64 packages of Sutent from that particular batch.

The fake Sutent originated from a Romanian supplier. As a consequence of this incident, Orifarm blacklisted that supplier. Another German importer, CC Pharma, had also unwittingly purchased counterfeit Sutent from a Romanian supplier in the autumn of 2013 and had completely stopped sourcing Sutent in Romania. In addition, CC Pharma had also blacklisted Sutent suppliers from Bulgaria, Hungary and Poland for the same reason.

The counterfeit Sutent sourced by Orifarm from Romania (photo by BfArM).

The BfArM recommended that patients carefully examine their Sutent capsules. The counterfeits purchased by the patient in Hamburg were relatively easily distinguished from the genuine capsules. Not only were they of a different colour and size, but they also lacked the Pfizer branding and the dose indication. The bottle containing the counterfeit capsules also exhibited subtle differences compared to the genuine Pfizer bottle. It goes without saying that taking a counterfeit cancer medication is likely to have severe health consequences for the patient.

CASE 2: OPERATION PANGEA VIII, JUNE 2015

(source: http://www.interpol.int/News-and-media/News/2015/N2015-082)

In June 2015, Interpol coordinated a global operation targeting the criminal networks behind the sale of fake medicines via illicit online pharmacies, resulting in 156 arrests worldwide and the seizure of USD 81 million worth of potentially dangerous medicines.

Operation Pangea VIII was the largest ever Internet-based operation focusing on the illicit sale of medicines and medical devices via the Internet, with the participation of 236 agencies from police, customs and health regulatory authorities from 115 countries. Private partners from the Internet and payment industries also supported the operation, which saw a record number of 20.7 million illicit and counterfeit medicines seized – more than twice the amount confiscated during the previous such operation in 2013.

The action resulted in the launch of 429 investigations, the suspension of 550 online adverts for illicit pharmaceuticals and 2,414 websites taken offline.

In addition to interventions on the ground, which included the discovery of an illicit warehouse full of counterfeit and expired medicines in Indonesia, the operation also targeted the main areas exploited by organised crime in the illegal online medicine trade: rogue domain name registrars, electronic payment systems and delivery services.

As well as raids at addresses linked to the illicit pharmaceutical websites, some 150,000 packages were inspected by customs and regulatory authorities, of which 50,000 were seized during the international week of action (9 – 16 June).

Among the fake and illicit medicines seized during the operation were blood pressure medication, erectile dysfunction pills, cancer medication and nutritional supplements. In the case from Indonesia, authorities uncovered an operation where criminals were altering the expiry date or the amount of the active ingredient on packages of counterfeit, expired and unregistered medicines at the warehouse and returning them to a pharmacy for sale.

This seemingly regular pharmacy in the UK was in fact unlicensed and selling illicit medicines online. It was shut down by UK authorities (photo by Interpol).

In the UK, authorities discovered an illegal online pharmacy selling unlicensed medicines obtained from another country. Police and the Medicines and Healthcare Products Regulatory Agency (MHRA) raided a premises connected to the website – which was arranged to look like a legal pharmacy – and seized 60,000 units of potentially dangerous medicines worth an estimated USD 2.4 million.

Direct impact

Based on country-level consumption data of medicines at wholesale prices, the difference between forecast sales and actual sales has been estimated for each country (Appendix A), and analysed using statistical methods (Appendix B), relating the sales shortfall to factors (called *variables* in economic parlance) such as:

- Growth rates of **Per capita Gross Disposable Income** of the household sector and **the exchange rate of the Euro vs other currencies** (socio-economic variables);

- **The percentage of the population reporting having bought counterfeit products as a result of being misled** as reflected in the **IP Perception study and the World Bank Index of Regulatory Quality**[14] growth rate (variables related to counterfeiting).

The rationale behind the selection of explanatory variables lies in the idea that differences between predicted and actual sales in a given country can be partly explained by economic or social factors (including both cyclical factors such as recessions and structural ones such as per capita income or demographic composition of the population), and partly by the consumers' propensity to infringe IP rights (sometimes unwittingly), as evidenced by responses to surveys such as the 2013 IP Perception Study by EUIPO, similar questions from Eurobarometer surveys, and indices related to corruption and quality of governance published by organisations such as the World Bank. The specific variables selected for inclusion in the analysis vary slightly from sector to sector, but inclusion of a variable from each of the two groups has been a common feature of all previous sectorial studies in this series.

The resulting estimates of the lost sales due to counterfeiting in the pharmaceutical sector, for all Member States, are shown in the figure below. This is the direct impact of counterfeiting discussed above, although as noted above, for this sector only the impact on the manufacturers and wholesalers is included, as opposed to wider considerations incorporating the retail trade sector.

For each country, the bars indicate the impact of counterfeiting on the legitimate sector's sales, expressed as a percentage of sales revenue at wholesale prices, while the diamonds indicate the 95% confidence interval of that estimate[15]. The figures represent an annual average for the six years 2008-2013.
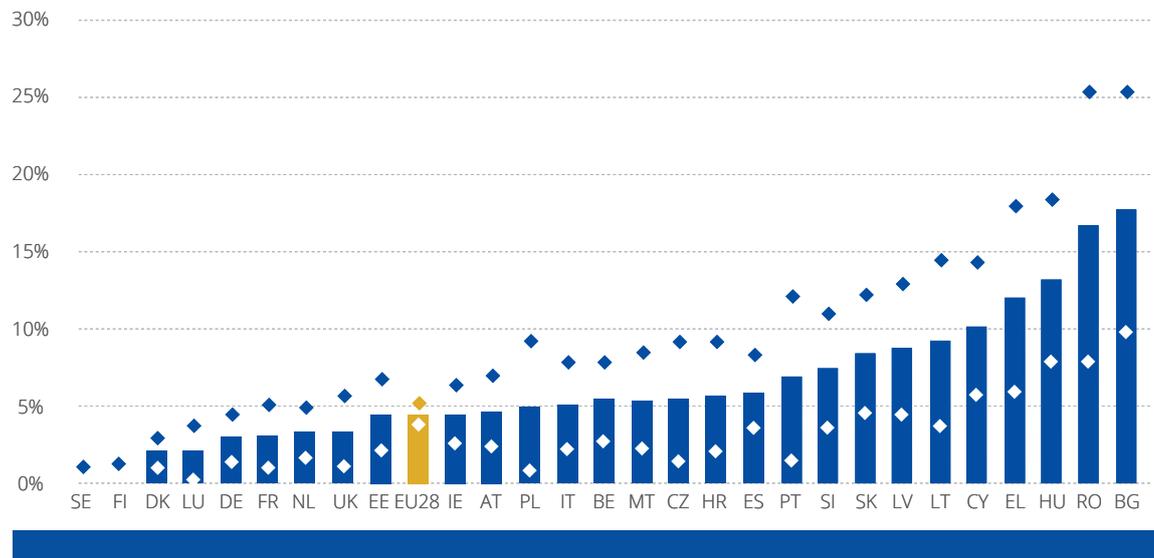
14 - The World Bank Index of Regulatory Quality captures perceptions of the ability of the government to formulate and implement sound policies and regulations that permit and promote private sector development.

15 - The 95% confidence interval is a statistical calculation which means that there is a 95% probability that the true figure lies between the lower and upper bounds of that interval. For example, for the EU as a whole, the estimated percentage of lost sales is 4.4%, with a 95% probability that the true percentage lies between 3.7% and 5.1%.

For the EU as a whole[16], the estimated total counterfeiting effect amounts to 4.4% of sales or €10.2 billion. This is a direct estimate of sales lost by legitimate manufacturers and wholesalers of medicines in the EU each year due to counterfeiting.

Country-level estimates of lost sales and associated confidence intervals, expressed both as a percentage of sales and in EUR, are shown in the table below.

	Lower 95%	Average	Upper 95%	Lost sales (million EUR)
AUSTRIA	2.4	4.6	6.8	109
BELGIUM	2.7	5.3	7.9	597
BULGARIA	9.8	17.6	25.4	160
CYPRUS	5.8	10.1	14.4	23
CZECH REP.	1.5	5.3	9.2	164
GERMANY	1.3	2.9	4.4	1,053
DENMARK	1.0	2.0	2.9	165
ESTONIA	2.0	4.4	6.7	14
GREECE	6.0	12.0	17.9	684
SPAIN	3.5	5.9	8.3	1,170
FINLAND	0.0	0.0	1.2	0
FRANCE	1.0	3.0	5.0	1,025
CROATIA	2.1	5.6	9.2	64
HUNGARY	7.9	13.1	18.4	416
IRELAND	2.5	4.4	6.4	513
ITALY	2.2	5.0	7.9	1,590
LITHUANIA	3.8	9.1	14.5	58
LUXEMBOURG	0.3	2.0	3.7	2
LATVIA	4.5	8.7	13.0	10
MALTA	2.2	5.3	8.4	6
NETHERLANDS	1.6	3.3	4.9	489
POLAND	0.7	5.0	9.3	363
PORTUGAL	1.5	6.8	12.2	281
ROMANIA	7.8	16.6	25.4	444
SWEDEN	0.0	0.0	1.1	0
SLOVENIA	3.7	7.3	11.0	53
SLOVAKIA	4.5	8.3	12.2	130
UNITED KINGDOM	1.0	3.3	5.7	605
EU28	3.7	4.4	5.1	10,188

The biggest absolute impacts of counterfeiting are observed in Italy (€1,590 million) and Spain (€1,170 million), both countries with relative effects of lost sales due to counterfeiting in medicines above the EU average (5% and 5.9% respectively). Germany and France present relative lost sales below the EU average at 3%, with absolute impacts of about one billion EUR each. Finally, in the United Kingdom, relative effects of counterfeiting in lost sales are below the EU average (3.3%) and total lost sales are €605 million.

Relative lost sales in Finland and Sweden are not significantly different from zero, meaning that there is no statistical evidence of sales in those two countries being affected by counterfeiting. It does not mean, however, that their pharmaceutical industries are not affected by counterfeiting of medicines, since they lose sales in other EU Member States as a consequence of the presence of counterfeit medicines in those markets.

17 - The total lost sales figure of €10.2 billion is not used to calculate employment impacts, since €1.8 billion of this total is attributable to imports. Therefore, the figure used to estimate employment impacts within the EU is €8.4 billion, representing the difference between estimated total lost sales and imports.

Since the legitimate industry sells less than it would have sold in the absence of counterfeiting, it also employs fewer workers[17]. Data from Eurostat on sectorial employment-to-sales ratios are used to estimate the corresponding employment lost in the legitimate pharmaceutical industry due to counterfeiting, resulting in a total of 37,700 lost jobs across the EU.

Direct employment impacts are calculated at the country level by estimating lost sales by that country's sector across the entire EU market. For example, the direct sales lost by the Italian industry as a result of counterfeit medicines are estimated by adding sales lost in Italy to sales of Italian medicines lost in other EU countries. The latter total is calculated from the differing counterfeiting rates prevalent within each Member States.

Germany is the biggest producer of medicines and also the country that loses the highest number of jobs the sector due to counterfeiting, nearly 7,000. Italy, France and Spain present significant loses in employment in the legitimate pharmaceutical industry, between three and four thousand jobs lost in each country. It should be noted that for the country-level estimation of lost employment, the losses are attributed to the Member States where the genuine medicines are manufactured, regardless of where in the EU the sales losses occur. This is why lost employment is higher in Germany than in Italy even though lost sales are €1.6 billion in Italy and €1.1 billion in Germany.

Indirect impact

In addition to the direct loss of sales in the pharmaceutical industry, there are also impacts on other sectors of the EU economy, as a sector suffering lost sales due to counterfeiting will also buy fewer goods and services from its suppliers, causing sales declines and corresponding employment effects in other sectors.

To assess this indirect impact, data from Eurostat[18] are used, showing how much the pharmaceutical industry buys from other sectors in the EU in order to produce what it delivers[19].

Final demand for medicines, as estimated in this report, includes imported goods (about 17% of total consumption) and not only the value of EU production (even though on balance the EU is a net exporter of medicines). Employment and indirect effects arising from these imports occur outside the EU and therefore are not included in the calculations. Consequently, of the total lost sales figure of €10.2 billion, only the value of domestic production (€8.4 billion) is used to calculate indirect impacts[20].

The total direct and indirect effect in the EU of lost sales due to counterfeiting, as an annual average for the period 2008-2013, amounts to €17.3 billion.

Thus, beyond the direct effects on the pharmaceutical industry (€10.2 billion in annual sales), an additional €7.1 billion are lost in other sectors of the economy due to counterfeiting. This is the *indirect* effect of counterfeiting[21].

Turning to employment, if losses in the supplier sectors are added to the direct employment loss in the pharmaceutical industry, the total employment loss resulting from counterfeiting is estimated at 90,900.

Total effects (direct plus indirect) are calculated at country level based on ESA 2010 harmonized IOT published by Eurostat and presented in the table below for the 7 Member States with the biggest total impacts.

18 - Input-Output Tables (IOT) published by Eurostat provide the structure of input requirements for the production of a certain final demand acknowledging whether the origin of these inputs is either domestic or imported. The IOT used in this report refer to year 2011 and are based in the new European System of Accounts (ESA) 2010 methodology.

19 - The IOT are provided by Eurostat at division level (2 digit NACE level) instead of class level (4 digit level). This means that for calculating the impact of the sales reduction in 21.20 and 46.46 NACE classes, it is necessary to use the structure of 'Basic pharmaceutical products and pharmaceutical preparations' (NACE 21) and 'Wholesale trade services, except motor vehicles and motorcycles' (NACE 46).

20 - On the other hand, this report only estimates the effect on sales of pharmaceuticals within the EU marketplace. So, to the extent that counterfeit products in non-EU markets displace exports of legitimate EU companies, there is a further employment loss in the EU which is not captured here.

21 - As mentioned in Section 1, this calculation assumes that the counterfeit products are produced outside the EU. If they are (partly) produced inside the EU, then the indirect impact would be less than shown in the table since those illicit producers would presumably source some of their inputs from EU producers.

	Direct effects				Total effects	
	Sales		Employment		Sales	Employment
	million €	%	persons	%	million €	persons
GERMANY	1,053	2.9%	6,951	2.7%	2,225	13,597
ITALY	1,590	5.0%	3,945	3.7%	1,874	10,631
FRANCE	1,025	3.0%	3,667	2.6%	1,851	9,212
SPAIN	1,170	5.9%	3,223	3.9%	1,233	9,911
UNITED KINGDOM*	605	3.3%	2,940	2.9%	1,167	7,747
IRELAND	513	4.4%	699	1.9%	868	1,320
NETHERLANDS*	489	3.3%	1,582	3.9%	705	4,197
EU28	10,188	4.4%	37,695	3.4%	17,338	90,880

*Based on ESA 1995 harmonized Input-Output Tables

The direct and indirect (and hence the total) effects on sales and employment reflect the structure and volume of production in each Member State, in particular the use of domestic inputs as well as different employment ratios.

As the biggest producer in the EU, Germany is the country most affected when total effects in sales and employment are considered, even though its direct sales losses only rank third, behind Italy and Spain, due to a comparatively modest relative effect in Germany.

22 - According to WIPO (2010) and OECD (2008), most of the empirical work assumes that counterfeiting occurs in informal markets that usually do not generate tax revenues.

Finally, the reduced economic activity in the legitimate private sector has an impact on government revenues[22] as well. Assuming that illicit producers and distributors do not declare their activities and the resulting revenues to the authorities, the lost taxes that sales of medicines valued at €10.2 billion would have generated can be calculated, as well as the tax revenues corresponding to the total (direct + indirect) loss of €17.3 billion calculated above.

23 - National Accounts tax aggregates are published by Eurostat and provide information on total payments for income taxes to all levels of government.

Two types of taxes have been considered[23]: taxes on household income and taxes on the income or profits of companies. In this report, VAT losses are not considered because medicines are subject to different VAT treatments depending on whether they are consumed at hospitals or at home, whether they are prescribed or bought over the counter and are sometimes not subject to VAT at all. To take those different distribution channels into account when calculating VAT losses would require many assumptions at the Member State level, and it was therefore decided to omit VAT from the calculation.

1) The lost household income tax, estimated on the basis of the share of wages corresponding to lost employment in total wages, considering direct and indirect effects on employment, amounts to €683 million.

2) The lost tax on corporate profits is estimated from the share of direct and indirect costs to industry and amounts to €206 million.

In addition, social security contributions linked to the direct and indirect employment losses are also estimated. Social security contributions data by industry are available in Eurostat, so that social security contributions per employee in each industry can be used to calculate lost contributions as a consequence of counterfeiting. These lost social security contributions amount to €802 million.

The total loss of government revenue (household income taxes, social security contributions and corporate income taxes) can therefore be roughly estimated at €1.7 billion.

ECONOMIC EFFECT OF COUNTERFEITING AND PUBLIC EXPENDITURE ON HEALTH CARE

Due to the special characteristic of the market for medicines, with public and private expenditure shares that vary widely across the EU, the relationship between public expenditure on health care as a percentage of GDP and lost sales due to counterfeiting of medicines in all EU Member States has also been analysed. The results of this analysis are presented in the chart below.
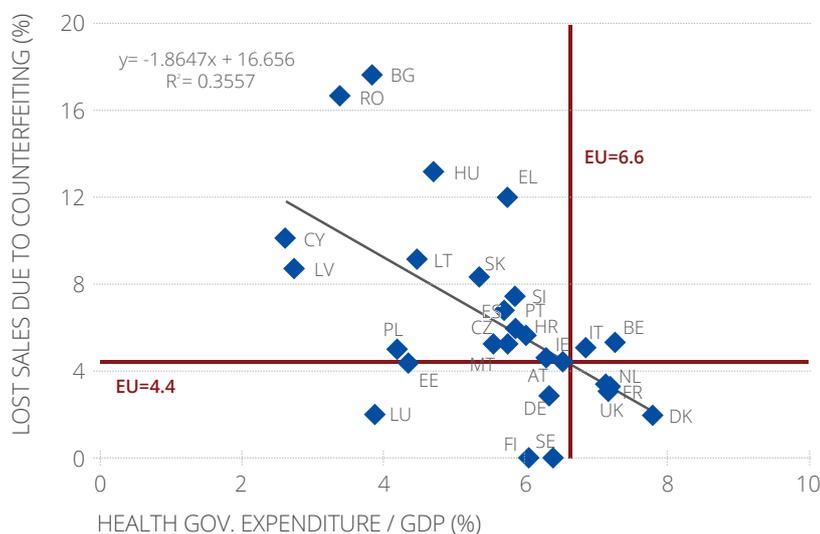
Public health care expenditure as a percentage of GDP averages 6.6% in the EU, as reflected in Eurostat statistics, with the lowest ratios in Cyprus and Latvia and the highest in Denmark.

A linear regression of the percentage of lost sales due to counterfeiting and the public health expenditure as a percentage of GDP is shown in the chart. There is an inverse relationship between the two, meaning that Member States with the highest public expenditure on health services as a share of the GDP in general have smaller losses of sales due to counterfeiting than do Member States where the public sector share is low. It is not clear which factors lie behind this relationship.

3. CONCLUSIONS AND PERSPECTIVES

The studies aiming to quantify the scale and impact of IPR infringements in cosmetics and perfumes, clothing and footwear, sports goods, toys and games, jewellery and watches, handbags and luggage, recorded music, spirits and wine and now pharmaceuticals have provided coherent estimates of the size of the problem of counterfeiting for legitimate businesses and for society in terms of lost sales, leading to lost jobs and loss of public revenue. These studies have used a common methodology and demonstrated the benefits of working in cooperation with stakeholders to take advantage of their knowledge of market conditions, while relying on harmonised European statistical data for the analysis.

The nine sectorial studies published to date will be followed in the coming months by other similar studies covering additional sectors, applying the same methodology and combining it with knowledge from industry stakeholders. These sectors include pesticides and other sectors, such as smartphones, depending on availability of data.

In parallel, the Observatory has carried out a joint study with the Organization for Economic Cooperation and Development (OECD) to estimate the value of counterfeit and pirated goods in international trade. That study, published in April 2016, estimated the value of international trade of counterfeit goods in 2013 at €338 billion (USD 461 billion) globally, corresponding to 2.5% of world trade. The corresponding figures for the EU were €85 billion (USD 116 billion), representing 5% of EU's imports from the rest of the world.

Taken together, these studies complement each other and provide a complete and objective picture of the impact of IPR infringements in Europe, in order to help policy makers develop effective enforcement policies.

APPENDIX A: THE FIRST STAGE FORECASTING MODEL

THE ECONOMIC COST OF IPR INFRINGEMENT IN THE PHARMACEUTICAL INDUSTRY

The methodology used for the estimation of the economic effects of counterfeiting is depicted in the following figure and explained in detail in this Appendix and in Appendix B.
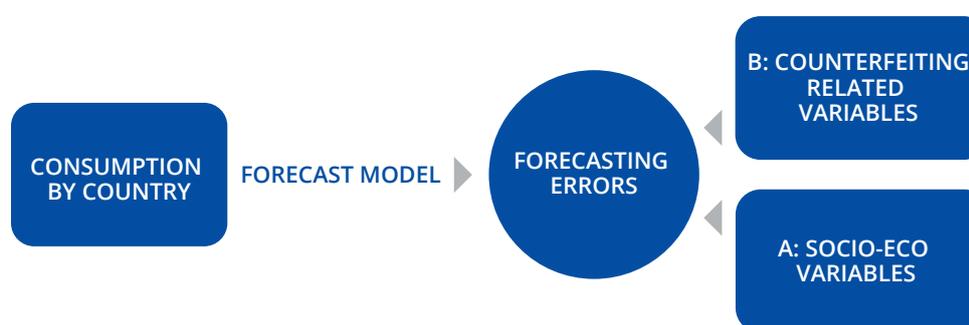
The first stage is comprised of a forecasting model of sales of products in each country. Assuming that a reasonably long time series of sales by country is available, a model is created that explains the trend of this time series and predicts the value of sales in subsequent years.

The simplest available comparable forecasts, across all member states, are produced via the use of ARIMA modelling. These models only use the past values of consumption to produce a forecast of future consumption. The forecast error, that is, the difference between the ARIMA forecast and observed sales, represents an estimate of the expected lost sales, notwithstanding adjustments for the impact of socio-economic factors.

The forecast error is the difference between predicted and actual consumption and for the purposes of comparability is expressed as a proportion of actual consumption, as shown in the following equation:

$$q^*_{it} = \frac{\hat{Y}_{it} - Y_{it}}{Y_{it}}$$

where Y_{it} is consumption in country i and year t (measured in EUR) and $\hat{Y}_{it}$ is the forecast of *Yit* obtained from the univariate model using consumption expenditure information up to and including the period t-1.

The relative error $q*_{it}$ measures the extent to which the forecasting model has predicted a higher or lower value (as a share of actual consumption) versus the actual level of consumption observed from the Eurostat data.

Step-wise forecast errors for the six years from 2008 to 2013 are constructed for Member States for which sufficient data is available, a total of 19 countries. It must be underlined that the one-period-ahead forecast errors estimated with ARIMA models follow a white noise process that is stationary and thus uncorrelated in time with zero mean and constant and finite variance.

The forecast errors are presented in the table below. It is evident that these errors exhibit a large degree of variability. However, the forecast errors are not interesting in themselves. The purpose of this study is not to produce a "good" forecast but rather to generate a set of relative errors which can then be quantitatively analysed to construct estimates of counterfeiting. Forecasts are produced using univariate models and using an automatic procedure, which ensures that they are comparable and "unpolluted" by a priori knowledge of factors influencing changes in demand.

RELATIVE ERRORS (%)	2008	2009	2010	2011	2012	2013
AUSTRIA	5.8	3.7	0.5	7.8	20.0	-5.4
BELGIUM	27.4	-27.8	-45.1	NA	-18.1	-31.8
GERMANY	5.7	-2.2	10.8	-5.7	2.8	-0.2
DENMARK	-3.7	2.0	-29.4	2.5	-13.3	1.1
SPAIN	-7.8	-4.3	13.2	19.0	7.2	4.8
FINLAND	-9.1	4.4	-2.3	5.3	-18.4	-19.8
FRANCE	NA	7.5	7.2	5.7	8.2	-1.3
HUNGARY	-17.4	13.8	-19.4	3.0	10.6	1.5
IRELAND	NA	-0.1	-17.0	18.6	-9.2	NA
ITALY	-2.1	6.9	3.4	11.8	28.8	3.9
LITHUANIA	-9.7	19.7	-10.8	-14.2	6.4	-8.9
LUXEMBOURG	3.1	-17.6	-3.8	-43.7	-9.2	-35.1
LATVIA	-2.9	-3.0	19.2	5.5	3.3	-27.9
NETHERLANDS	-47.9	-11.0	-39.3	-19.5	4.2	-14.6
POLAND	-7.2	26.8	2.2	-0.7	31.9	-8.8
PORTUGAL	-6.8	-5.9	-6.6	2.1	2.5	5.8
SWEDEN	19.2	-13.0	-0.4	-12.8	-38.9	NA
SLOVAKIA	-9.2	-5.9	0.7	16.3	25.2	18.0
UNITED KINGDOM	22.9	35.1	-0.5	55.6	-10.5	-17.0

The second part of the estimation process seeks to determine to what extent these forecast errors can be explained by economic variables and by variables related to counterfeiting.

APPENDIX B: THE SECOND STAGE ECONOMETRIC MODEL

THE ECONOMIC COST OF IPR INFRINGEMENT IN THE PHARMACEUTICAL INDUSTRY

Counterfeiting might be one of a number of factors impacting on the level of legal sales of medicines, but there are, as outlined earlier, a series of other economic factors which can explain the differential, such as variables related to the economic capacity of households, or consumer demographics (e.g. population growth) or any other driver of consumption expenditure.

Having accounted for the influence of economic variables on the sales differential, an attempt is made to assess the extent to which counterfeiting variables, or relevant proxies, can explain the propensity to purchase fake medicines. These variables might include measures of consumer and market characteristics, as well as the evolution of a country´s legal environment.

Combining the economic and counterfeiting variables allows for the specification of an econometric model whose aim is to explain the aggregate differential (forecast errors) between expected and real sales. The model is specified in the following format:

$$q^*_{it} = \alpha * X_{it} + \beta * Z_{it} + \varepsilon_{it}$$

where X^{it} is a matrix of explanatory variables unrelated to counterfeiting and Z^{it} a matrix of variables related to counterfeiting. Finally, ε_{it} is the remaining error.

Socio-economic variables considered to have explanatory power, **unrelated to counterfeiting,** include:

1. Gross Disposable Income (GDI) of the household sector: per capita income and growth;
2. GDP per capita and GDP growth;
3. Exchange rate of Euro vs. other EU currencies;
4. Population growth.

24 - A list of factors affecting demand and consumption for counterfeit goods is available in OECD (2008).

The second term of the equation, Z_{it}, contains the matrix of **variables thought to be related to counterfeiting**[24]. These variables include:

1. Population at risk of poverty or social exclusion, as a share of total population and growth;

2. Distribution of income by quartiles (including the share attributed to the lowest quartile and the ratio between the highest and lowest quartiles);
3. Gini coefficient (a measure of income inequality);
4. Several variables selected from the Observatory's IP Perception study[25] and from Eurobarometer (including counterfeiting and corruption related variables);
5. Corruption Perception Index, CPI (level and growth);
6. Intellectual Property Right Index;
7. Worldwide Governance Indicators (World Bank) covering Government Effectiveness, Regulatory Quality, Rule of Law and Control of Corruption (level and growth);
8. Public expenditure on medicines and health services, as a percentage of GDP, per capita and growth rate.

Variables 1 to 4 in the list are considered to be consumer-related drivers of demand for counterfeiting. The population at risk of poverty, the share and concentration of income in quartiles of the household income distribution, along with the Gini coefficient, are all variables that describe degrees of income inequality.

The variables considered for inclusion in the Z matrix from the IP Perception study and the Eurobarometer include: the percentage of the population that has bought counterfeit products intentionally or been misled into the purchase of counterfeit products; the purchase of counterfeit pharmaceuticals; and the percentage of the population that considered, in certain circumstances, buying counterfeit products to be acceptable.

Corruption variables considered for inclusion in the Z matrix from the Eurobarometer survey include[26]: the percentage of the population declaring that corruption is widespread, that it is in the business culture, that it is a major problem and the percentage of the population that believed corruption had increased over the last three years. And from the Tolerance Index to Corruption, the measure covering the percentage of the population that declares that corruption in public administration or public service is acceptable was considered.

Variables 5 to 7 are considered to be drivers of counterfeiting related to institutional characteristics of each country.

The Corruption Perception Index (CPI) is published by Transparency International and measures how corrupt public sectors are seen to be by the public in each country. In this study the updated index is used as a time invariant variable with reference year 2012.

The Intellectual Property (IP) Rights Index used is published by Property Rights Alliance and measures the strength of protection accorded to IP. The 2010 index is used in this study and the same value is used for each country across the six years studied as a time invariant variable.

25 - Available at: https://euipo.europa.eu/ohimportal/en/web/observatory/ip_perception.

26 - In WCO (2012) it is stated that: 'The predominance of the informal is then associated with corruption and the degree of regulation…' So, to the extent that counterfeiting is part of the informal economy, a measure of corruption could be considered explanatory for counterfeiting.

The Worldwide Governance Indicators reflect the perception of government effectiveness, regulatory quality, rule of law and corruption. They are published annually and range from 2.5 for favourable aspects of governance to -2.5 for poor. These indicators are considered as potential proxies for the perceived risk of buying or selling counterfeit goods. These indices have a high negative correlation with poverty indicators and with the variables from the IP Perception study and Eurobarometer.

The rationale behind these variables is that in countries where the population exhibits a high degree of acceptance of counterfeit products and where governance and rule of law are perceived to be weak there is a higher likelihood of consumption of a product to be illicit than in countries with good governance, strong rule of law and low corruption.

Finally, the public expenditure on medicines and health services reflects market characteristics that might also be related to counterfeiting. The idea is that in countries where public institutions purchase a high share of medicines it could be more difficult for counterfeit products to infiltrate the legitimate distribution channels.

Altogether, 63 different explanatory variables were tested and different econometric techniques were applied in order to select a model with robust econometric results and a clear interpretation.

Some of the variables considered in the modelling process are clearly correlated with each other. High correlation coefficients between explanatory variables (referred to as multicollinearity) present a common problem in econometric analysis. If correlated explanatory variables are included in the model, the estimated coefficients for these variables could be mistakenly considered as insignificant (small t-statistics), although possessing a high overall significance for the model as measured by the F-test. This situation can pose problems when trying to interpret the meaning and significance of parameter estimates and when testing the significance of other variables in the model specification.

For instance, per capita GDI of the household sector and per capita GDP are highly correlated and also per capita public expenditure in health services is highly correlated with misled purchase of counterfeit goods from IP Perception study.

Therefore only those variables with the greatest explanatory power are included in the model in order to avoid the problems described above.

Different methods have been applied and the preferred model is estimated using Weighted Least Squares (WLS) with the Standard Errors of forecast errors from ARIMA models used as weights. This method solves problems of heteroscedasticity as stability of variance of estimated residuals is a requirement for an acceptable accuracy in the coefficients estimation.

Finally, residuals were analysed to check compliance with the usual assumptions of regression models[27].

MODEL RESULTS

The results of the final estimated model are shown in the table below.

Variable	Coefficient	Standard Error	t Statistic	95% Confidence interval	
				Lower	Upper
Constant	-0.1196	0.0450	-2.66 ***	-0.2088	-0.0304
Per capita GDI growth	-0.0020	0.0034	-0.59	-0.0088	0.0048
Euro exchange rate growth	1.0165	0.4922	2.07**	0.0406	1.9925
IP Perception: buy counterfeit mislead	0.8049	0.4709	1.71 *	-0.1289	1.7387
WB Index: Regulatory Quality (growth)	-0.6421	0.3332	-1.93 *	-1.3029	0.0186

R-square between = 11.1%

Wald Chi-2 statistic = 4.3 ***

* significant at 90% confidence level
** significant at 95% confidence level
*** significant at 99% confidence level

The econometric model explains 11% of total variance of the stage 1 forecast errors. The model uses a combination of two economic variables and two counterfeiting-related variables. For each variable, the first column shows the estimated coefficient, the second column shows the standard error, while the third column indicates the statistical significance of the parameter estimates[28].

The explanatory variables, not related to counterfeiting are **per capita Gross Disposable Income growth** with a negative coefficient (not statistically significant); and the **Euro exchange rate** with a positive coefficient, implying that as the euro appreciates, so does the capacity for counterfeiting outside the Euro zone.

27 - All results of the diagnostic tests are available on request.

28 - If, for example, an estimated coefficient is significant at the 95% confidence level, then one can say that the probability that the true coefficient is zero and the estimated value was obtained solely by chance is 5%. The "t-statistic" shown in the third column is simply the estimated coefficient divided by its standard error. The last two columns show the 95% confidence interval for the coefficient; in other words, the true coefficient lies in the interval between the lower and upper bounds with a 95% probability.

The remaining two variables relate to counterfeiting and include one variable from the IP Perception study and one of the Worldwide Governance Indicators from the World Bank. The variable from IP Perception study is the **percentage of the population declaring having bought counterfeits as a result of being misled** and it is a time-invariant variable with a positive coefficient, meaning that the percentage of population declaring having bought fakes is positively related to counterfeiting.

The **Regulatory Quality Index** published by the World Bank captures perceptions of the ability of the government to formulate and implement sound policies and regulations that permit and promote private sector development. The coefficient estimated for this variable is negative, so that a higher growth rate of the index in a particular country corresponds to improving quality of regulation and is related to smaller forecast errors.

As the main objective of the model is to estimate the coefficients of the counterfeiting-related variables, the characteristics of these coefficients should be investigated. Several models have been estimated, adding different explanatory variables, using different econometric techniques and also based on sales at consumer prices. The resulting estimated coefficients for the counterfeiting-related variables are presented in the following table, providing a good indication of its stability.

	IP Perception	WB Regulatory Quality
1 (chosen model)	**0.8049**	**-0.6421**
2	1.4298	-
3	1.0339	-0.9876
4	1.1631	-0.9397
5	-	-0.9397
6	0.6038	-0.4604
7	0.5091	-0.5006
8	-	-0.4564
9	0.6819	-0.4484
10	0.8489	-0.4434
11	0.6819	-0.4484
12	0.5764	-
Average 2-12	**0.8365**	**-0.6250**

Based on coefficients estimated for the counterfeiting-related variables presented above, the impact of counterfeiting is estimated via the following relationship:

$$C^*_{it} = \widehat{\beta}_1 * Z_{1i} + \widehat{\beta}_2 * Z_{2it}$$

Where C^*_{it} represents the sales lost due to counterfeiting in country i in year t (expressed as the fraction of the sector's actual sales), Z_{1i} is the value of the IP Perception variable, and Z_{2it} is the value of the World Bank Index growth rate in that country and year[29]. The β's are the estimated coefficients from the table at the beginning of this section.

The counterfeiting effect is calculated for all 28 EU Member States, applying the coefficients estimated in the model above to the values of the explanatory variables.

Interpretation of this specification is made on the following basis: for a country where 3% of the population declares having bought counterfeit products as a result of being misled and the average growth rate of Regulatory Quality index in 2008-2013 is -4%, the effect of counterfeiting on legitimate sales of medicines is a sales decrease of 5% (0.8049*0.03 - 0.6421*(-0.04) = 0.0498).

29- It should be noted that in this case, the value of Z1i is the same for all t since the variable is time-invariant during the period covered by this study.

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THE ECONOMIC COST OF IPR INFRINGEMENT IN THE PHARMACEUTICAL INDUSTRY

Quantification of infringement in Manufacture of pharmaceutical preparations (NACE 21.20)

EU IPO
EUROPEAN UNION
INTELLECTUAL PROPERTY OFFICE
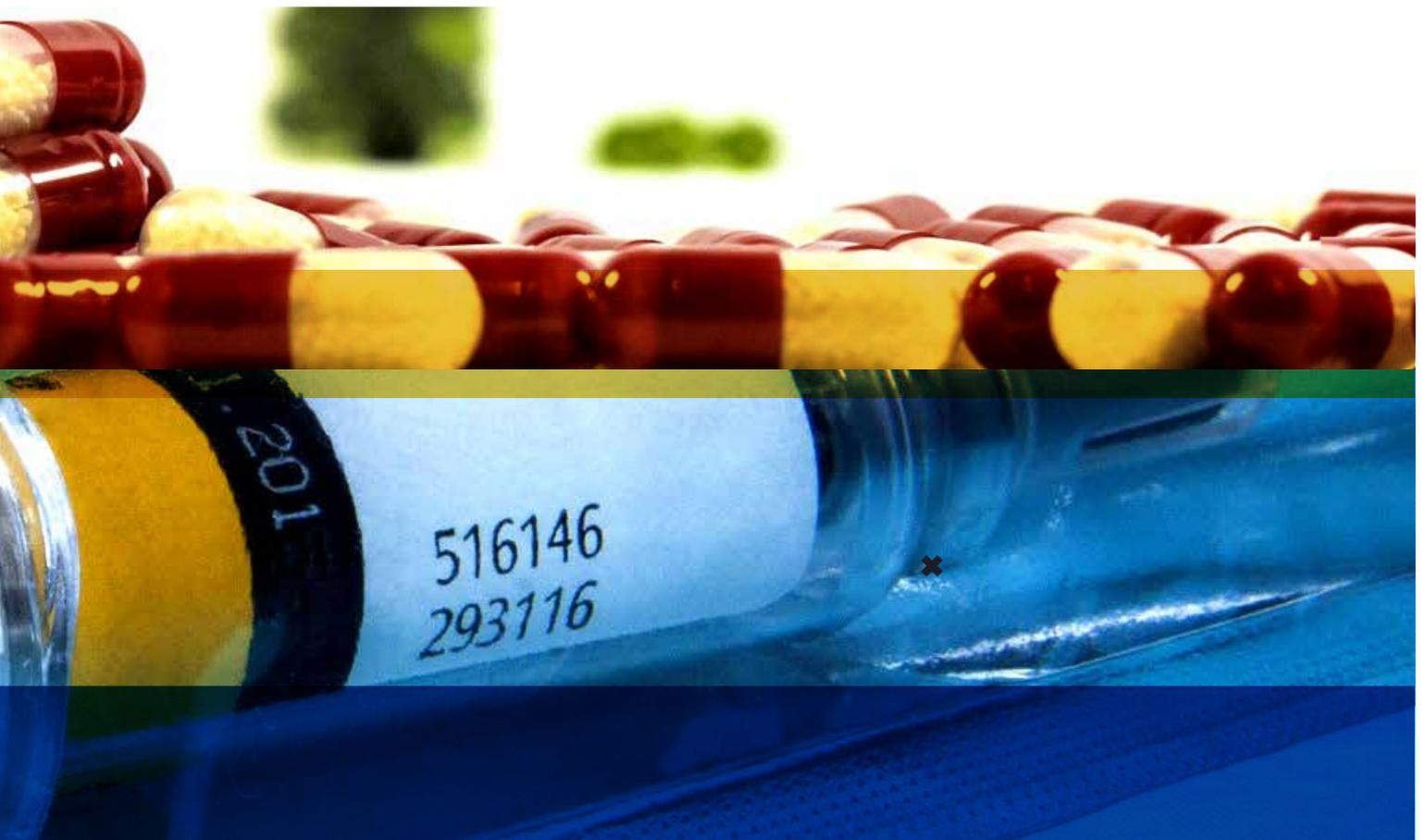
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E-03008 - Alicante
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