

Ricardo Luiz Sichel

Federal University of the State of Rio de Janeiro, Candido Mendes University, Brazil
e-mail: rlsichel@yahoo.de

COUNTERFEITED DRUGS – THE ECONOMIC IMPACT

FAŁSZOWANIE LEKÓW – ZNACZENIE EKONOMICZNE

DOI: 10.15611/pn.2017.474.18

JEL Classification: H51, I11, K11, K42

Summary: The problem of counterfeited medicines causes expenditures for the health institutions and public authorities, especially when public health service is concerned. It also causes an expressive loss for the public budget, because of less taxes paid or jobs lost, which has as consequence the payment of welfare money. Moreover, it is also a huge net of illegal activities that finance other forms of illicit activities, such as terrorism, drugs, etc. The paper analyses the economic impact of the trade of illegal products from the perspective of brands which are recognized by consumers and in the context of social interest and problems of public health that are related to the use of inadequate products or medicaments which contained substances that damage the health. It is concluded that the administrative measures that have to be undertaken cannot be limited to the national authorities but should be the result of international cooperation.

Keywords: counterfeited drugs, medicaments, economic impact.

Streszczenie: Problem fałszowania leków powoduje wydatki podmiotów leczniczych i państwa, zwłaszcza w kontekście publicznej służby zdrowia. Rodzi on również znaczne straty dla budżetu, ponieważ obniżone są wpływy podatkowe, zmniejsza się liczba miejsc pracy, a w konsekwencji rosną wydatki na opiekę społeczną. Ponadto, powstała rozległa sieć finansowania działalności przestępczej, w tym terroryzmu i handlu narkotykami. Artykuł analizuje wpływ handlu nielegalnymi lekami z perspektywy powszechnie rozpoznawalnych marek, ale również w kontekście interesów społecznych i problemów dla służby zdrowia związanych z istnieniem nieodpowiedniej jakości produktów, a także tych, które mogą szkodzić zdrowiu. Konkluzją jest stwierdzenie, że powzięte środki zaradcze nie mogą być realizowane przez władze krajowe. Niezbędna jest współpraca międzynarodowa.

Słowa kluczowe: fałszowane leki, produkty lecznicze, wpływ ekonomiczny.

1. Introduction

One of the major problems of the public authorities is the implementation of an adequate health policy. It includes not only the treatment of a certain disease, but also the distribution of medicaments, where part of its price is paid with public funding and the performance of a preventive policy as well. The purpose is to spend public money adequately.

In this context, the local authorities are challenged with the threat of illegal trade of medicaments. There are different forms of execution of this prohibited activity. One of them is by smuggling the article to a certain country. It is also possible to introduce the counterfeit product *via* online shopping and illegal pharmacies, which pretend to be a legal establishment, in order to mislead the consumer. Another form of trading this illegal activity happens in legal pharmacies, but the dealers involved in the transaction acquire the product from non-trustable suppliers.

This kind of business exposes the member of the society to a significant risk, because he believes he is acquiring the product in a legal pharmacy and that it has the therapeutic purpose that is advertised. On the contrary, the counterfeit product has not the therapeutic purpose that the original one has, it does not help in the treatment of the disease to be treated and may have in extreme situations toxic elements in its composition that puts the health of the consumer at risk.

The figures related to counterfeit products worldwide are enormous. It is a huge net of illegal activities that finance other forms of illicit activities, such as terrorism, drugs, etc. They also cause an expressive loss for the public budget, because of less taxes that are paid, the more jobs are lost which has as consequence the payment of welfare money.

All these figures demonstrate the importance of this topic which is not limited to an economic analysis, but also has a key impact on a national health policy. Therefore, it is important to describe the impact of counterfeiting in specific areas, starting with the pharmaceutical industry.

2. The counterfeited drugs

The impact of the trade of illegal products is based on the brands which are recognized by the consumers because of their quality, performance and also the idea of belonging to a certain group of clients who are able to afford a certain product or service. They don't play an important role if the trademark is not considered by the client or if the product/service is badly rated. OECD observes [2016, p. 11]: "Counterfeiting and piracy matter in an innovation driven global economy. Intellectual Property (IP) is a key value generator for firms, helping them succeed in competitive markets. At the macroeconomic level, IP protection and enforcement is one of the main drivers of innovation, which contributes to long term economic growth. Given the fundamental

economic importance of IP, counterfeiting and piracy must be directly targeted as a threat to sustainable IP-based business models”.

The counterfeit products involve the violation of the Patent Law. The application of the norm may be a consequence of a legal, ethical and political discourse. The political discourse has always played an important role in patents, because of the monopoly granted. The point is how to understand the law. Its semantic is determined by using and justifying a norm in order to integrate to a certain system [Wroblewski 1978, p. 83]. The patent legal rules, as a consequence of the WTO Agreements, are a part of international treaties and conventions and cannot be locally implemented, as it used to be in the past. The activities of its titleholder are to be considered in worldwide scale and the consequences of piracy affect the countries, not only in the field of intellectual property, but also considering its national security.

3. The pharmaceutical industry

According to Cialis Online [2016], there are four main types of counterfeit medicaments:

1. “Dummy drugs”. As a rule, the main active agent in these fake medicaments simply doesn’t exist. Incidentally, this does not mean that they have not been treated. It is proved that a placebo (this term is applied by doctors for “dummy drug”) is no worse than a genuine drug. Theoretically, it’s taking is harmless.

2. Imitators of drugs. The main active agent is usually replaced by a cheap and less effective component. This is the most dangerous fake: there is no guarantee that the replacement will not cause a fatal outcome.

3. Changed medications. They contain the same active agent as the genuine medicament but in larger or smaller amounts. It is also dangerous. You are not guaranteed any therapeutic effect or absence of serious negative effects.

4. “Drug copies”. This is the most common form of fake medicaments in the world. These “medicaments” contain the same substances as the original, and in the same amounts. However, you don’t know where and from which producer, a manufacturer bought the substance (active agents) for pills. At first glance, they are innocent tablets. But this type of counterfeiting is more dangerous than “dummy drugs”. These remedies are not subjects of quality control. In other words, buying a fake, you rely on the conscience of the underground pharmacist.

Pfizer [2007] also states the most counterfeited medicaments:

- Lipitor,
- Viagra,
- Novarsc,
- Zoloft,
- Celebrex,
- Aricept,
- Diflucan,

- Feldene,
- Ponstan,
- Vibramycin.

According to Wajzman [2016, p. 10] there are several ways to use a medicament, which can be showed by Fig. 1.

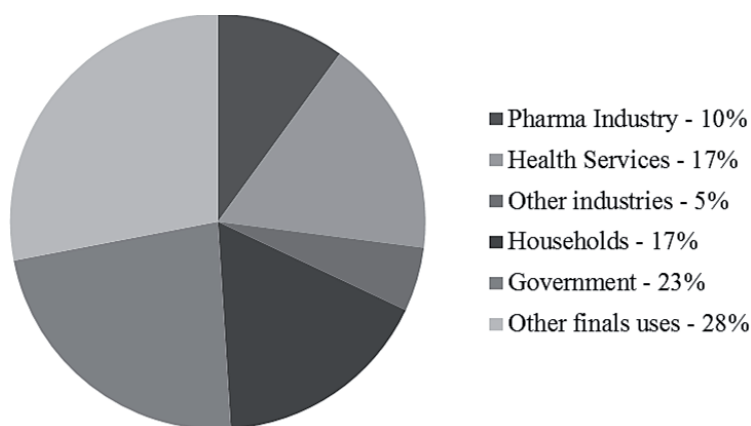


Fig. 1. Ways to use a medicament

Source: [Wajzman 2016, p. 10].

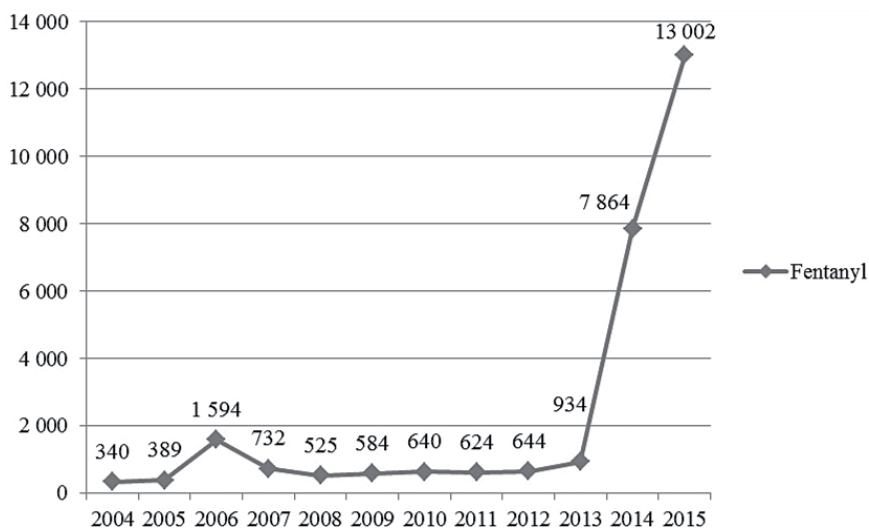


Fig. 2. Number of fentanyl exhibits in NFLIS, 2004–2015

Source: [DEA 2016].

The DEA [2016, p. 5] points out the increasing number of counterfeit medicines including 4.3 million non-medical users of pain relievers in the USA in 2014. These pharmaceutical products made of fentanyl were the induction of more people to be drug dependents, because of the products used for their fabrication. They are also undermining the action of authorities to enforce the abuse of opioid medicaments. Figure 2 shows the number of fentanyl medicaments in the USA from 2004–2015.

Figure 3 shows the origin of those counterfeited medicaments containing illicit fentanyl [DEA 2016, p. 3]:

1. Fentanyls in powder form and pill presses are shipped via mail services.
2. The powder fentanyls are processed and mixed with heroin, or sold as heroin and pressed into pills and sold in the Canadian drug market.
3. The powder of fentanyls are processed and mixed with heroin, or sold as heroin, or pressed into pills and sold in the United States drug market.
4. The powder of fentanyls are cut and diluted for further smuggling, or pressed into counterfeited prescription pills.
5. Precursors for manufacturing fentanyls are shipped via mail service.
6. Precursors are used to manufacture fentanyls in clandestine laboratories.
8. Precursors are likely used to manufacture fentanyls in clandestine laboratories

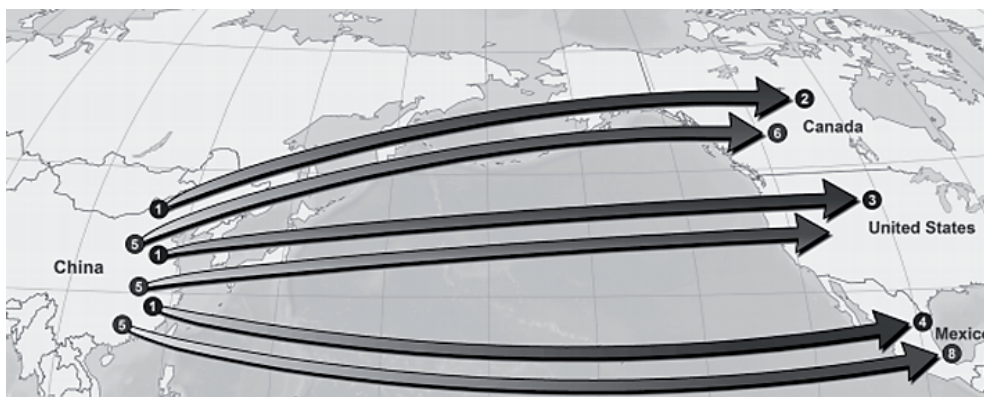


Fig. 3. Origin of those counterfeited medicaments containing illicit fentanyl

Source: [DEA 2016, p. 3].

One possible consequence of the rise of this kind of trade is an increasing number of drug dependants, overdoses and deaths. The expansion also threatens major public health policies, especially related to the control of certain types of medicines.

According to the World Health Organization [Nursing School 2014] 60% of the counterfeited drugs are antibiotics, hormones, analgesics, steroids and antihistamines, according to Fig. 4.

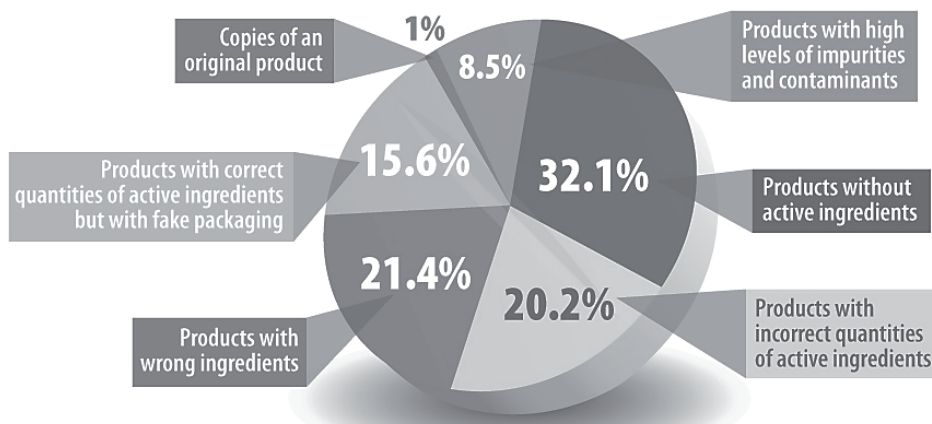


Fig. 4. Counterfeited drugs by types

Source: [Nursing School 2014].

It is also possible to observe a connection related to the top best selling drugs (Fig. 5) and the counterfeited products. This association is linked in the way the consumer feels about the product [Nursing School 2014].

Top 10 Best Selling Drugs of 2012		PRODUCT (Manufacturer)	Sales
NEXIUM	(AstraZeneca)		\$5,989,000,000
ABILIFY	(Otsuka America)		\$5,870,000,000
CRESTOR	(AstraZeneca)		\$5,092,000,000
ADVAIR DISKUS	(GlaxoSmithKline)		\$4,889,000,000
CYMBALTA	(Lilly)		\$4,720,000,000
HUMIRA	(Abbvie)		\$4,609,000,000
ENBREL	(Amgen)		\$4,337,000,000
REMICADE	(Centcor)		\$3,876,000,000
COPAXONE	(Teva CNS)		\$3,581,000,000
NEULASTA	(Amgen)		\$3,460,000,000

Fig. 5. Top 10 best selling drugs of 2012

Source: [Nursing School 2014].

There is an obvious relation between the counterfeited products and those trademarks listed above. It has also an impact of technologies developed by the major pharmaceutical industries. Sanofi-Aventis for example has developed some strategies, such as [Sanofi-Aventis 2016, p. 5]: the development of an exclusive label and the inclusion of a traceable system, based on bar codes.

According to Wajsman [2016, p. 5] the pharmaceutical industry loses about 10 billion Euros as a result of fake products, which corresponds to 4.4% of the sector's sale. The consequences have also impact on the jobs. Approximately 38,000 jobs are lost as a consequence of this illegal praxis. The impact on the EU economy is about 17 billion euro, with an employment loss of 91,000 jobs and 1.7 billion euro in government revenues [Wajsman 2016, p. 5].

Two important cases should be mentioned, in order to demonstrate the magnitude of the problem. The first one happened in Germany [Wajsman 2016, p. 12], where the Federal Institute for Drugs and Medical Devices requested that the German pharmacies should examine their stocks of parallel-import of the medicament Sutent, whose active ingredient is used for certain types of cancer. The larger supplier of this medicament is Orifam which imports it from the EU Member States. After a contact made in 2014, in Hamburg, and consultations made to Orifam, the company decided to recall 64 packages of Sutent, because of the fake product which had its origin in Romania. The fake product could be identified by comparing the colours and the different size of the capsules. It is likely that the counterfeit product may have caused severe health damages.

The second one was the Operation Pangea VIII [Wajsman 2016, p. 13], in June 2015, which was a coordinated global operation with the purpose of inhibiting the sale of fake medicaments, *via* illicit online pharmacies. The result was: 156 arrests worldwide and the apprehension of US\$ 81 million value of potentially dangerous products. The operation took place in 115 countries, with the participation of 236 agencies and the target of illegal sales of medicaments and medical devices via internet. The result was: the beginning of 429 investigations, the suspension of 550 online advertisements and 2414 websites taken offline. There was a variety of fake products investigated, such as blood pressure medicaments, erectile dysfunction pills, cancer medication and nutritional supplements. In the UK authorities also discovered unlicensed selling of medicaments, which website pretended to be a legal organization and seized 60.000 units (estimated value of US\$ 2.4 million).

According to the report [Wajsman 2016, p. 17] made, the following conclusion can be made, related to the impact of this illegal form of trade: "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."

There are also different impacts to be considered. At a first level, this illegal form of business causes the loss of an expressive number of jobs, which has a direct impact on the domestic budget, depending on the type of social security protection. The tax evasion should also be considered as well as the financing of other illegal activities, such as drugs and terrorism. The tax evasion is estimated in 10.2 billion

euro (sales tax). Considering the total of direct and indirect taxation, the value is about 17.3 billion euro. On the other hand, there is a loss of sales for the private sector, such as in Germany (1.1 billion euro) and in Italy (1.6 billion euro). This tax evasion causes a serious financial problem for the national governments, especially if considered its impact on the national budget.

The social and health problems resulting from this kind of illegal activity must also be considered. The loss related to social security contributions is 802 million euro. On the other hand, the health agencies have also to deal with the consequences of these illegal activities because they inflict wellbeing problems to the consumer, who believes in the legality of the product he is buying. Public health expenditures have an average percentage of 6.6 in the EU [Wajsman 2016, p. 20].

In Brazil, in the period of 2005 to 2010, there was an increase of 92% of apprehension of counterfeited drugs, in products worth US\$ 75 billion [Ames 2012]. Ames points that according the WHO there are many factors that contribute to this illegal practice, such as the absence of appropriate legislation and proper supervision, weak penal sanctions. It is also mentioned that according to the Brazilian Sanitary Surveillance Agency, drugs related to sexual impotence are the main type of counterfeited drugs. Figure 6 shows the greatest percentage of counterfeited drugs seized by the Brazilian Police from 2007 until 2010.

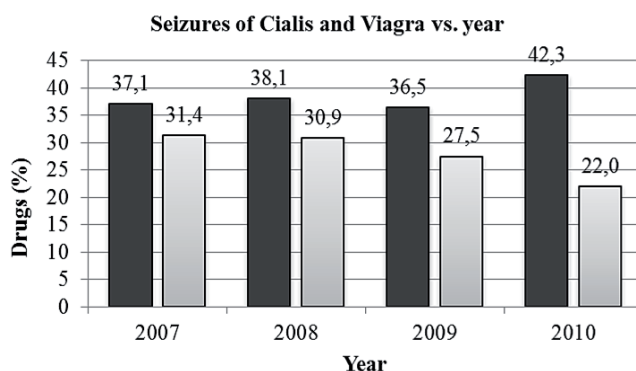


Fig. 6. Counterfeited drugs against erectile dysfunction seized by the Brazilian Police from 2007 until 2010
Source: [Ames 2012].

According to the Brazilian Authorities there are many reasons why those illegal products were commercialized. The first one is related to the fact that there is no obligation to show or retain a medical prescription and the second one is based on the high cost for buying the original product [Ames 2012].

It is obvious that those illegal activities are quite profitable. But the social interest and the problems of public health that are related to the use of inadequate products or even medicaments which contained substances that damage the health must also

be considered. All those factors have also an important impact on national security measures, since those activities finance drug, terrorism and other illegal activities. Therefore it is necessary to strengthen the international cooperation in order to combat this activity. On the other hand, this activity has an impact on the expected income of the company. It imposes new security costs and implicates in devaluating the value of its asset, including the trademark of the copied product. The consequence of this is the loss of jobs and profitability for many companies and the value of the intangible goods itself must also be taken into account.

4. Conclusions

The problem related to the counterfeited medicines is not restricted to health damages caused. It also causes expenditures for the health institutions and public authorities may be involved, especially when public health service is concerned. On the other hand, it has also an impact in the combat of terrorism and organized crime financing, where money laundry is often used.

This form of trade causes also damages to the treasury authorities because of tax evasion. It is therefore not only a health problem, but also a part of the security policy and cannot be dealt at a national level, but has to be part of a global negotiation in order to establish a mechanism of fighting this form of illegal praxis. The exchange of information of the intelligence authorities is also vital for an efficient combat of the international counterfeit business. If the governments could cut the financing of the illegal activities related to this kind of actions they will be making an important step to reduce it, which will have consequences for public health policies.

At a global level the trade of counterfeited goods in 2013 was about 338 billion euro. The administrative measures that have to be undertaken can't be limited to the national Authorities but should be the result of international cooperation.

References

- Ames J., 2012, *Counterfeiting of drugs in Brazil*, São Paulo: Revista de Saúde Pública, vol. 46, no. 1.
- Cialis Online, 2016, *How to check Cialis pack and detect a counterfeit medicament?*, <http://grademeds.com/how-to-check-cialis-pack-and-detect-a-counterfeit-medicament.html> (2.01.2017).
- DEA, 2016, *Counterfeit Prescription Pills Containing Fentanyl: A Global Threat*, Drug Enforcement Administration, Washington, DC.
- Nursing School, 2014, *The effects of counterfeit medication*, <http://www.nursingschoolhub.com/effects-counterfeit-medication> (16.01.2017).
- OECD, 2016, *Global trade in fake goods worth nearly half a trillion dollars a year – OECD & EUIPO*, <https://www.oecd.org/industry/global-trade-in-fake-goods-worth-nearly-half-a-trillion-dollars-a-year.htm> (2.01.2017).
- Pfizer, 2007, *Counterfeit pharmaceuticals*, Pfizer, New York.
- Sanofi-Aventis, 2016, *Drug Counterfeit*, Sanofi, Paris.
- Wajzman N., 2016, *The Economic Cost of Infringement in the Pharmaceutical Industry*, Euiipo, Alicante.
- Wroblewski, J., 1978, *Legal reasoning in legal interpretation*, Logique Analysis, vol. 12, p. 3–31, Centre national de recherches de logique, Bruxelles.