**THREATS OF TRADE IN COUNTERFEIT MEDICAL PRODUCTS**

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**ABSTRACT**

The outburst of the COVID-19 pandemic two years ago had a strong impact upon the increment of on-line trade in goods. This applies to the on-line trade in pharmaceutical products, as well. Different criminal networks used the COVID-19 pandemic for widening the scope, as well as the scale of their operations in on-line trade in unauthorized pharmaceuticals, as well as fake pharmaceuticals for medical treatment of different medical conditions including COVID-19.

Trade in counterfeit medical products does not only mean illegal exploitation of intellectual property rights under the TRIPS Agreement and is a serious threat to the economic growth. It also jeopardizes the life, health and safety of a national economy citizens undermining the good governance, the rule of law and citizens’ trust in government.[[1]](#footnote-1)

**Key words:** on-line trade in goods, counterfeit medical products, international regulative on intellectual property rights, TRIPS, exemptions from TRIPS for pharmaceutical products.

INTRODUCTION

Trade in counterfeit goods is as old as trade itself. At present, however, instead of being traded through informal markets, counterfeit goods, due to globalization trends and tendencies, make their way into the legitimate distribution channels. Intensifying on-line trading and supplying small consignments to individual purchasers enabled criminal networks to increase the scope and the scale of their criminal activity in trade of counterfeit goods. The creation of digital trading space made monitoring of international markets and illegal trade activities much more difficult, as purchasing does not take place on any known physical location or market place. Instead, small parcels are delivered directly to final consumers through legitimate supply chains, thus making the delivery almost invisible for the customs and other relevant authorities. The detection of on-line counterfeit trade is very difficult considering the intense dynamics of changes within the digital space and disappearance of traditional ways of doing business and trade exchange of goods.

It also has to be taken into account that the virtual space is devoid of national territorial borders, thus detection of counterfeit products becomes a global problem for which national regulation becomes ineffective. In the past, in most of the cases buyers, sellers and goods were all in the same geographical area at the time of transaction. At present, the seller (as an on-line store) may be registered in one country, the products may be in a warehouse in another, whereas the buyers may be all around the world. Each of the jurisdictions where the buyers, the seller and the goods are located might have different laws on intellectual property, or some of them even not have such laws at all. On-line shopping allows transactions to be executed without parties ever seeing with or even directly communicating to one another. The evasive role of internet has flooded new channels that drive the use by counterfeiters and pirates, amongst which are the increasingly used apps and social media platforms. But also, counterfeiters misuse the advantages of the operational free trade zones, of multilateral trade facilitation measures and of national economies where government standards are considered to be insufficient.

The Illicit Trade Report (2019) prepared by the OECD and the EU Intellectual Property Office (EUIPO) recorded a significant increment of trade in counterfeit and pirated goods. According to their findings, at the end of 2016, 3.3% of world trade and up to 6.8% of the EU import from third countries was trade in counterfeit and pirated goods.[[2]](#footnote-2) One of the most important trends that influenced the growth of trade in counterfeit and pirated goods was the small parcels’ boom. The latest report released in 2021 claims that in the period from 2017-2019 more than 50% of the detentions of counterfeit goods in the European Union were related to on-line transactions. Over 90% of detention cases related to e-commerce were shipped to the EU by mail/post, although measured in terms of value this figure represents only 14% of the value of seized goods.[[3]](#footnote-3) In relation to this, the World Customs Organization Report on illicit trade shows that 53.4% of the pieces seized in 2019 violating IPR in the world were caught by mail.[[4]](#footnote-4)

Besides a number of jointly effectuated analyses on global trends in counterfeit and fake goods trade, the OECD and the EUIPO also provided a report on trade in counterfeit medical products. According to this report, the increment of on-line trade of counterfeit goods creates serious damage to the economic growth and jeopardizes benefits of internationally protected intellectual property rights. However, this problem is even greater when talking about trade in counterfeit medical products has to be taken in consideration that it is a direct threat to human life, human health and consumers’ safety. Fake pharmaceuticals are reported to be not properly formulated in most of the cases and may contain dangerous ingredients. They also include medicaments for serious diseases such as malaria, HIV/AIDS and cancer. In 2016 the total amount of counterfeit pharmaceutical products reached 4.4 billion American dollars. Last but not least, trade in counterfeit pharmaceutical products undermines the good governance, the rule of law and citizen’s trust in government, and can ultimately threaten political stability.[[5]](#footnote-5)

Having on mind the gravity of the problem deriving from global trade in counterfeit medical products, the authors of this paper first pay due attention to the correct definition on falsified medical products, as well as on the actual international and multilateral regulative on intellectual property rights relevant for pharmaceuticals and exemptions thereof; provide analyses of actual global trends and greatest traders of such products; and finally present concluding remarks.

International/multilateral regulative on intellectual property rights in the pharmaceutical industry and definition of falsified medical products and

International/multilateral regulative on intellectual property rights is the fundamental instrument used in prevention of abuse of patents and licenses and is the fundament of the combat with counterfeit goods, including counterfeit medical products. Multilateral conventions on protection of industrial property and authors’ rights enacted back in the second half of the 19th century have been still in force. Yet, the global multilateral system enhanced protection of intellectual property rights not only through the World Intellectual Property Organization (WIPO), but also through the World Trade Organization (WTO). Both WIPO and the WTO contribute to harmonization of national laws and regulative with international and multilateral regulative on protection of intellectual property rights.

WIPO was established as a self-funded agency of the UN in 1967. Its establishment was enacted by adoption of a convention (a WIPO Convention), which currently support 193 member-states. WIPO is a global forum on intellectual property (IP) services, policy, information, and cooperation which administers the following international conventions and treaties on protection of industrial property and copy rights, i.e. the Paris Convention for the Protection of Industrial Property from 1883; the Berne Convention for the Protection of Literary and Artistic Works from 1886; the Madrid System for the International Registration of Marks from 1989; the Trademark Law Treaty (TLT) adopted in 1994; the Nice Agreement, the Vienna Agreement, and the Nairobi Treaty, all of which regulate specific aspects of trademarks or specific symbols, but provide no provisions related to counterfeits or prevention of illicit practices; the Hague Agreement Concerning the International Registration of Industrial Designs adopted in 1925; the WIPO Copyright Treaty (WCT) from 1996.[[6]](#footnote-6) Looking at international conventions and copy rights administered by WIPO it is obvious that the agency deals with legal instruments that are used as legal tools on protection of intellectual property rights, yet it lacks regulation on situations when it comes to an infringement of the protected rights

The World Trade Organization (WTO) adopted the so called Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) which is the most comprehensive legal document related to intellectual property rights up to date, as it covers all intellectual property trade related issues at multilateral level. It covers the following intellectual property rights: copyright and related rights; trademarks and service marks; geographical indications and origin appellations; industrial designs; patents; the layout-designs of integrated circuits; and undisclosed information including trade secrets and test data.[[7]](#footnote-7)

The TRIPS Agreement guarantees exclusivity of usage and exploitation of, as well as of benefits of protected intellectual property rights. Regarding protection patents, this agreement provides three exemptions. Article 27 of TRIPS stipulates that from patent protection are exempted:[[8]](#footnote-8)

* inventions banned for commercial usage in order to protect ethics and public order, which covers inventions that might endanger life and health of humans, animals and plants or could jeopardize the leaving environment;
* diagnostic, therapeutic and surgery treatment methods used for healing humans or animals;
* production of plants and animals, except of microorganisms and biological procedures for plant and animal production, i.e. non- biological and microbiological procedures.

By registering a patent, according to the TRIPS Agreement, the owner of the patent gains exclusivity for its usage and exploitation of benefits thereof, as well as the right to prevent third parties to produce, to use, to offer for sales or to export patented products without a consent of the patent owner. Nevertheless, TRIPS defines provisions on so-called compulsory licensing, when the government decides to use a patent without a consent of the patent owner. This usually happens in the pharmaceutical industry, i.e. in production of medicines in specified untypical circumstances in the global economy. These provisions were brought under *the Declaration on TRIPS agreement and public health* proposed at the Doha Ministerial Conference in 2001, amended at the Ministerial Conference in Cancun and enforced in 2017 when it was accepted by 2/3 of the WTO member-states.[[9]](#footnote-9) TRIPS perceives that medical products produced with compulsory licensing should be offered for sales not only on domestic markets, but also should be exported and sailed abroad. This amendment was included into TRIPS in order to facilitate distribution of pharmaceutical products and drugs in the least developed countries and support their health systems. Since, this provision was has been used only once in the case of Ruanda for importation of triavir from the Canadian Apotheks.[[10]](#footnote-10) The evidence confirmed that implementation of compulsory licensing is a time consuming and very expensive procedure and the costs of its implementation overcome the benefits for the developing country. Thus this has been the one and only practical experience of its implementation since.

Unlike the WIPO, TRIPS contains provisions referring explicitly to counterfeit products. In its preamble it acknowledges the negative impact of counterfeit products in international trade, and, recognizes the need for a multilateral framework of principles, rules and disciplines dealing with international trade in counterfeit goods.[[11]](#footnote-11) Each member-state of the WTO has an obligation to adopt measures on any act of infringement of intellectual property rights, including remedies for prevention of infringements, as well as remedies which can serve as deterrent to further infringements. Member-states must ensure enforcement and protection of intellectual property rights in civil, administrative, and even criminal procedures. They also must grant national courts power to order provisional or interim measures in situation of threats of imminent irreparable harm and authorize customs authorities to exercise border measures to sanction infringements.[[12]](#footnote-12) Member-states are expected to cooperate with each other in order to eliminate international trade in goods infringing intellectual property rights.[[13]](#footnote-13)

The World Health Organization (WHO) is one of the international organizations and agencies actively involved in the combat with falsified medical products. For this purpose it has established a WHO Member State Mechanism as a global platform where member-states can convene, coordinate, decide and organize actions to address substandard and falsified medical products. Back in 2013 the WHO launched a Global Surveillance and Monitoring System aimed to provide countries a tool for reporting incidents of substandard and falsified medical products.[[14]](#footnote-14)

To help member-states to properly report on incidents on substandard and falsified products, the WHO defines three categories of medical products subject to international trade exchange that should be payed special attention, i.e. *substandard, unregistered/unlicensed* and *falsified medical products*.[[15]](#footnote-15)

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| --- | --- | --- | --- | --- |
| **SUBSTANDARD** |  | **UNREGISTERED/UNLICENSED** |  | **FALSIFIED** |
| Also called “out of the specification”, these are all medical products that fail to meet either their quality standards, or their specifications or both. | Medical products that have not undergone evaluation and/or approval by the NRRA\* for the market which they are marketed/distributed or used, subject to permitted condition under national or regional regulation and legislation. | Medical products that deliberately/fraudulentlymisrepresent their identity, composition or source.  |

Figure 1: Classification of medical products used in the context of the World Health Organization Global Surveillance and Monitoring System and the Member States Mechanism[[16]](#footnote-16)

WHO warns all member-states and final consumers that substandard and falsified medical products can be found among all main therapeutic categories such as medicines, vaccines and in vitro diagnostics, although the most reported substandard and falsified medical products happen to be anti-malarias and antibiotics. They contribute to antimicrobial resistance and drug resistance infections. Generic and innovator medicines, regardless of their price, may be falsified and this applies both for very expensive products for cancer but also for inexpensive products such as pain killers.[[17]](#footnote-17)

These products are usually produced in very poor and unhygienic conditions with usage of unqualified personnel. They may contain unknown impurities, and due to disrespect of good producing practices of the pharmaceutical industry, may be contaminated with bacteria.

Falsified medical products may contain no active ingredient or the wrong amount of the correct active ingredient. They also usually contain corn or potato starch or chalk.[[18]](#footnote-18) However, they very often contain dangerous ingredients that may cause serious injuries, even deaths, such as blue printer ink, amphetamines, arsenic, boric acid, brick dust, cement powder, floor polish, leaded road paint, nickel, shoe polish, etc.[[19]](#footnote-19)

Definition presented in Figure 1 states that falsified products are medical products that deliberately/fraudulently misrepresent their identity, composition or source. Such products are often very difficult to be identified, as they appear to be identical to the genuine product, although they do not produce the same effect in disease treatment which in certain cases may lead to lethal outcome. Consumers in all countries in the world are at serious risk to be victimized by being involved in purchases of counterfeit medical products without even being aware of it. Yet, the WHO states that low- and middle-income countries, areas with conflicts and civil unrest, as well countries with weak health systems are at biggest risk in regard of counterfeit medical products. WHO recommends not only to pay attention to the correct look and color of the purchased medicine, but also to check its smell, its packaging, the present spelling mistakes and grammatical errors, the manufacturing and expiry dates and to check whether data presented on the outer packaging match those in the inner packaging.[[20]](#footnote-20)

Another international agency involved in combat of counterfeit medical products is also the United Nations Office on Drugs and Crime (UNDOC). In May, 2019, the UNDOC issued a Guide to Good Legislative Practice - Combating Falsified Medical Product – Related Crime. This is a very useful tool for all interested in general provisions and definitions of counterfeit medical products; recommendations on preventions for the supply chain of counterfeit medical products and relevant data basis for research, exchange and analysis; classifications of offences in the area and definitions of liability of legal person; definition of prosecution of offences; information on national and international cooperation; and protection of and assistance to witnesses and victims.[[21]](#footnote-21)

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