

THE DANGER OF ORGANIZED CRIME IN THE AREA OF FALSIFICATION OF MEDICINES AND MEDICAL PRODUCTS (PROFIT VS. RIGHT TO HEALTH)

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ABSTRACT

Falsification of medicines and medical products as major risk to human life and health is new global threats facing the international community. By its nature, counterfeiting medicines and medical products as a very lucrative “business” falls under the term of organized crime. Precisely because of the large profits it is considered to be a new danger and one of the priorities for all countries in the fight against organized crime, especially because of its role in financing of terrorism. In the phenomenology of organized crime, represented by criminal associations, of the so-called adaptable or flexible type, the participation of counterfeiting and falsification of medicines and medical equipment is taking on an increasing share. In these organized activities legal entities are increasingly involved, which are companies that, due to profit, have no regard for what most the important goods for the individual or society are. Fake pharmaceutical products endanger not only public and individual health, but also the economy, because they “feed a parallel economy”. A global problem is the illegal sale of counter-

feit or fake medicines and medical products through websites that are difficult to detect or are the result of fraud by manipulating corporate websites. Although this trade has previously been recognized as a growing danger to human health, the pandemic of the disease COVID-19 has brought “to the light of day” countless glaring cases of organized trade in counterfeit medicines and, moreover, various fake low-quality medical equipment as new opportunities for profit. Enormous quantities of such equipment (protective masks, vaccines, disinfectants, home tests, antimalarial drugs, etc.) have appeared in different modus operandi of criminal trade, from fraud in large shipments, online sales of equipment with fake labels to direct package delivery. The expansion of the online trade in counterfeit pharmaceutical products through the Internet space of the Dark Web has significantly developed organized crime as the so-called “mafia super business”. Moreover, illegal and legal markets are often intertwined in many ways. Although international legal frameworks have been established with bodies to combat very dangerous forms of transnational organized crime, such as Interpol, Europol, OLAF, etc., there are a number of difficulties in detecting and prosecuting illegal trade in counterfeit and fake medicines and medical products, especially in developing countries. Given that legal companies are also engaged in this trade, as direct traders or intermediaries, and that the connections between criminal networks facilitate the infiltration of such medical equipment into the legal supply and sales chain, in detection operations it is necessary, in addition to the police, to include the participation of customs, tax, inspection and health authorities. From the perspective of legislation and jurisprudence, this is a demanding challenge for the rule of law and a great risk for fundamental human rights, because the scale of trade, the development of the illegal market and the cross-border cooperation of organized criminal networks with counterfeit medicines and medical equipment represent a significant public health problem. From the perspective of public health danger and global security the problem is so worrying that it has led to the idea of declaring this crime an international crime. This paper will include a presentation of legal frameworks for combating counterfeiting medicines and medical products, as well as the operations of various bodies undertaken with the aim of prosecuting perpetrators. The goal of the treatment of criminal liability in this paper is the investigation of the problems of detection and suppression of an organized network of production and distribution medical counterfeits.

Keywords: counterfeit medicines and medical equipment, Dark Web, fake medicines, organized crime, legal entities

1. INTRODUCTION

Globally, around two billion people do not have access to necessary medicines, vaccines medical and other equipment, which opens up a huge and very profitable area of trading in falsified medical products.¹ The World Health Organization (WHO) has estimated it involves a market of 75 billion dollars and that falsified medicines make up more than 10% of the global pharmaceutical market while Interpol estimates that the profit from such crime amounts to 4.4 billion US

¹ See *Substandard and Falsified Medical Products*, World Health Organization (WHO), available at: [<https://www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products>], Accessed 15 February 2024.

dollars yearly.² A significant share of fake products (estimated at almost 30%) is present in developing countries and in under developed countries such as Asia, Africa, and Latin America³ where citizens, due to the inaccessibility of medicines and medical equipment and lower costs, are exposed to dangerous falsifications (mostly medicines for malaria, HIV/AIDS tuberculosis and those for treating life threatening conditions).⁴ At the same time, in developed countries the use of fake medicines such as painkillers, hormones, steroids, antibiotics etc. as lifestyle medicines has increased. These include Viagra or weight loss concoctions.⁵ The use of those products is dangerous for public health because not only are they ineffective in curing sickness, but they are harmful due to the poisonous substances in them because of which numerous cases have resulted in death.⁶ Fake medicines directly and indirectly globally affect public health, leading to an increase in sickness, resistance to medicines, unsuccessful treatment, death and ultimately in an increase in health care costs and in a loss of trust in the healthcare system. From the public healthcare danger perspective, the problem is of such huge concern that it has even led to the idea that this crime be declared an international crime that is, a crime against humanity.⁷ Also, the falsification of medicines belongs to white collar crime and can be called the “perfect crime”, because by the time a fake medicine is even suspected, the fraudsters have disappeared and covered their tracks.⁸ It is a generally accepted opinion that the falsification and illegal sale of medicines

² The Organization for European cooperation and development (OECD) and the European Union Office for property rights (EUIPO) in 2020 estimate that the total value of falsified pharmaceutical products sold worldwide is almost 4.03 billion EUR. According to Kurtović Mišić, A.; Sokanović, L.; Mišić Radanović, N., *Kažnjiva ponašanja fizičkih i pravnih osoba za vrijeme pandemije COVID-a 19: između kaznenog, prekršajnog i upravnog prava*, Zbornik radova Pravnog fakulteta u Splitu, 2, 2021, p. 425.

³ Cooper, J. M., *Intellectual property piracy in the time of the metaverse*. IDEA: The Law Review of the Franklin Pierce Center for Intellectual Property, Vol. 63, No. 3, 2023, pp. 479-517.

⁴ Islam, I.; Islam, M. N., *A blockchain based medicine production and distribution framework to prevent medicine counterfeit*, Journal of King Saud University - Computer and Information Sciences, 36, 1, 2024.

⁵ Glass, B., *Counterfeit drugs and medical devices in developing countries*, Dovepress, Research and Reports in Tropical Medicine 2014, 5, pp. 11–22.

⁶ In Nigeria in 2009 a cough medicine syrup containing antifreeze for motorcars killed 84 children. In those countries falsified medicines can be found for example in markets, and in Guinea 60% medicines sold are fake. See Przyswa E., *COUNTERFEIT MEDICINES AND CRIMINAL ORGANIZATIONS*, Report IRACM, Paris, 2013, p. 17.

⁷ See Attaran, A.; Bate, R.; Kendall, M., *Why and how to make an international crime of medicine counterfeiting*, Journal of International Criminal Justice, 2011, Vol. 9, No. 2, pp. 325-354.

⁸ The physician and legitimate pharmaceutical company (or both) must prove that the diagnosis or legitimate medicine did not cause the patient's ensuing damage or disease. Nelson, M.; Chang, D., *Counterfeit Pharmaceuticals: A Worldwide Problem*, The Trademark Reporter 96, no. 5 (September-October 2006), p. 1070.

are an „ideal“ transnational crime and that a mafia type of organizations views the fake medicine market as an inexhaustible source of income without greater criminal risk.⁹

The fake medical products trade underwent a renaissance during the outbreak of the COVID-19 pandemic. The thesis is correct that the fraud related to the production and trade of nonstandard and counterfeited medical products has followed the spread of the coronavirus.¹⁰ The pandemic has led to the transformation of organized crime, because up till then, narcotic merchants in the search for high profits, and with considerably lower risk of prosecution, very quickly „turned to“ counterfeiting pharmaceuticals.¹¹ Furthermore, the significantly lower punishments for selling counterfeit pharmaceuticals than for the sale of narcotics make this type of crime more profitable and less risky. The pandemic brought „to the light of day“ innumerable blatant cases of organized trade in not only counterfeit medicines but in even more varied, poor quality medical equipment and products. Huge poor quality and falsified protective masks, vaccines, disinfectants, house tests, antimalaria and antiviral medicines etc. have emerged worldwide using various *modus operandi* of criminal trade. „Vaccine “against corona virus could be found in that illegal trade even before the emergence of the first real vaccines.¹² The expansion of online trade via Dark Web („a web of crimes“) even further

⁹ Delval, P., *Counterfeit Medicines, Défis: Le Intelligence Stratégique au Service de la Compétitivité*, 2015, no 5, p. 15. i 21, According to Hall, A.; Koenraadt, R.; Antonopoulos, G., *Illicit pharmaceutical networks in Europe: organising the illicit medicine market in the United Kingdom and the Netherlands*, Trends in Organized Crime; New York, 2017, Vol. 20, 3-4, p. 297.

¹⁰ Sokanović, L.; Roksandić, S.; Stošić, I., *Pravo na zdravlje vs. krivotvorenje medicinskih proizvoda u vrijeme pandemije COVID-19*, International Congress Journal “3. KONGRES KOKOZA I 5. HRVATSKI KONGRES MEDICINSKOG PRAVA S MEĐUNARODNIM SUDJELOVANJEM”, Rovinj, 2022, p. 78. i Roksandić, S.; Grđan, K., *COVID-19 i razumijevanje pravnih propisa vezanih uz suzbijanje zaraznih bolesti u Republici Hrvatskoj – osvrt na bitna pravna pitanja od početka pandemije do listopada 2020.*, Pravni vjesnik, Vol. 36, No. 3-4, pp. 327-343.

¹¹ Bate, R., *Making a killing: the deadly implications of the counterfeit drug trade*. AEI Press, Washington, D.C., 2008. Profit gained by counterfeiting medicines often totals 3000% and it is estimated that investing 1000 USD in counterfeit script medicines can result in a profit of 30 000 USD, which is 10 times more than the profit from trafficking heroin. According to Blackstone, A. E.; Fuhr, P. J. Jr.; Pociask, S., *The Health and Economic Effects of Counterfeit Drugs*, American Health & Drug Benefits, 2014, 4, p. 220. A comparison of the difference in the profitability of the production of heroin and Viagra shows that the production of 1 kg of heroin has higher costs and a lower street value than the corresponding costs and profits of 1 kg of Viagra. In a case investigated by the Medicines and Healthcare Products Regulatory Agency in the UK, 100,000 counterfeit pills imported at around 25p each were sold for up to £20 each. See Clark, E., *Counterfeit Medicines: The Pills That Kill*, in Telegraph, 5 April 2008, [<http://www.telegraph.co.uk/health/3354135/Counterfeit-medicines-the-pills-that-kill.htm>], Accessed 15 February 2024.

¹² Bracci, A.; Nadini, M.; Aliapoulos, M. et al., *Dark Web Marketplaces and COVID-19: before the vaccine*, *EPJ Data Sci.* 10, 6, 2021, p. 3.

developed organized crime in the form of so called „Mafia super business“. Panemics change the structure of opportunity of organized crime¹³ but the danger to health will impact generations. By its nature, counterfeit medicines belong to the concept of organized crime.

In the phenomenology of organized crime, represented in criminal associations of the so called adaptable or flexible type, counterfeit medicines and medical products are taking up a greater share. Increasingly, legal entities are included in those organized criminal activities, that is, trading and other commercial companies and it is becoming a serious worldwide problem which include production networks and distribution which are key components of so called „industrialized organized crime“. ¹⁴ A globalized virtual space and health crises have transformed organized criminal activity because of a wider circle of consumers. As reason for the huge increase in counterfeit medical products is, among other things, the increasing sophistication of counterfeiting methods.¹⁵ This paper will present the most important operations undertaken within the international legal framework and the national criminal law possibility of fighting against counterfeiting of medical products. Changes in the way criminal networks operate during the pandemic will be presented, as well as the difficulties of detecting organized networks of production and distribution of medical counterfeits. In conclusion, the aim of this paper is to point out the far reaching social, economic and political consequences of profit acquired by counterfeiting medical products on the part of criminal associations and the global danger to the right to health as a fundamental human right and the great threat to world security.

2. CONCEPTS OF FALSIFIED AND COUNTERFEIT MEDICINES AND MEDICAL EQUIPMENT

For the purposes of further developing this topic, it is useful to firstly clarify definitions of concepts because official definitions differentiate fake and counterfeit medicines. Fake medicines contain poor quality or wrongly dosed ingredients or are intentionally or fraudulently marked in regard to their identity or source or are falsely packaged, contain wrong ingredients or low levels of active ingredients.¹⁶

¹³ Muggah, R., *The COVID-19 Pandemic and the Shifting Opportunity Structure of Organized Crime*, in *A Multidisciplinary Approach to Pandemics: COVID-19 and Beyond*, Bourbeau, P., (ed.), 2022.

¹⁴ Dégardin, K.; Roggo, Y.; Margot, P., *Understanding and fighting the medicine counterfeit market*, Journal of Pharmaceutical and Biomedical Analysis, 87, 2014, pp. 167-175.

¹⁵ Casabona, C. M. R.; Mora, A. U.; Jimenez, P. N.; Alarcon-Jimenez, O., *International strategies in fighting against medicaments fraud and other similar offences. The MEDICRIME Convention*, Crime, Law and Social Change, 2017, Vol. 68, No. 1-2, pp. 95-122.

¹⁶ European Medicines Agency (EMA) and *Substandard and Falsified Medical Products*, *op. cit.*, note 1.

Fake medicines are designed to imitate real medicines while counterfeit medicines are those not in keeping with intellectual property rights or breach the law on copyright logos.¹⁷ Therefore, falsified medicines (generic and brand products) intentionally falsely labelling their source or identity and are manufactured and sold, containing misleading information about the manufacturer, authenticity and effectiveness.¹⁸ The concept of falsifying medical equipment includes every medical product falsely presented.¹⁹ From the criminal law aspect, what is key in counterfeiting is precisely malicious behavior, that is, intentional fraud. Besides these concepts, in use are the concepts of poor quality medicines (substandard medicines) which signify “real medicines which do not satisfy the specifications of quality set for them”²⁰ and the concept of unlicensed pharmaceutical medicines.²¹ According to Interpol, “pharmaceutical crime“ includes production, sales and distribution of fake, stolen or inadmissible medicines and medical equipment and includes counterfeiting and falsifying medical products and their packaging and accompanying documentation, as well as theft, fraud, unallowed redirection, smuggling, illegal sale of medical products and related money laundering.²²

3. CHANGES IN ACTIVITY OF ORGANIZED CRIME DURING COVID-19 PANDEMIC

Criminologically, the COVID-19 pandemic is a significant factor in the phenomenology of organized crime and its transformation. At the beginning of the crisis and measures of social distancing and quarantine in 2020, there was a fall in certain types of violent and non-violent crimes.²³ However, anti-pandemic

¹⁷ Altavilla, A., *Safe, Innovative and Accessible Medicines in Europe: A Renewed Strategy for Patients and the Pharmaceutical Sector*, European Journal of Health Law 25, No. 2, 2018, p. 137.

¹⁸ Kopp, S., *WHO survey on terminology on “counterfeit” medicines or equivalent*, 2019. According to Islam, I.; Nazrul Islam, M., *op. cit.*, note 4.

¹⁹ *Counterfeit Medicines and Organised Crime*, United Nations Interregional Crime and Justice Research Institute, Turin, 2012, p. 14, and Xuereb, S.; Valenzia, A., *The Difference between Falsified and Counterfeit Medicines*, February 14, 2018.

²⁰ *Counterfeit products. Trends in Organized Crime*, 2013, Vol. 16, No. 1, pp. 114-124.

²¹ This can be generic products legally produced abroad but are sold in the country via contracts on licensing so they can circumvent the existing laws on intellectual property. Hall, A.; Koenraadt, R.; Antonopoulos, G., *op. cit.*, note 9, p. 298.

²² Negri, S., *The Medicrime Convention: Combating Pharmaceutical Crimes through European Criminal Law and beyond*, New Journal of European Criminal Law, 2016, Vol. 7, No. 3, p. 356.

²³ The pandemic reduced so called „street crime“, but widened to scope of other crimes trafficking in protective equipment for combatting coronavirus. Streltsov, Y., *Coronavirus and Criminal law: Paradox or Expediency of the Joint Analysis?!* In the greater part of North America and Western Europe the number of murders and violent attacks went down, in Chicago, Los Angeles and New York the number of burglaries and rapes went down. Muggah, R., *The Pandemic Has Triggered Dramatic Shifts in the Global Criminal Underworld*, 2020.

measures did not stop narco-cartels and gangs so on an international level the effects of the pandemic were precisely expansion of organized pharmaceutical crime through the illegal distribution chains of vaccines and medicines against corona.²⁴ Criminal associations usually quickly reacted to ways of making profit and the pandemic opened up new opportunities due to the dramatic increase in the demand for certain medical products,²⁵ causing “dramatic changes in the global criminal underworld”.²⁶ A health crisis emerged which did not only demand adaptation only from many legal companies but also from criminal associations.²⁷ By introducing restrictive measures narco-cartels were faced with stopped supply chains, reduced profits and market changes. With lockdown, mandatory quarantine, limited travel and border closure, the Mexican narco-cartels drug production was reduced due to reduced imports of necessary chemical substances from China while supply chains for sale of cocaine to the USA and Europe were cut.²⁸ Mexican cartel Jalisco New Generation quickly became one of the leading manufacturers of stolen and pirated pharmaceutical products, as a part of a successful global black market in counterfeit or stolen medicines and personal protective equipment.²⁹ At the same time, Columbian and Mexican narco-cartels at the beginning of the pandemic, changed their *modus operandi* gaining social control in local communities with a tradition of the use of violence by demonstrating solidarity and care for people.³⁰ Branches of Cosa Nostra and Camorra used to deliver basic essentials to populations of the Italian towns of Palermo and Naples. Cartels in Mexico (in the states of Jalisco, Veracruz etc.) used to deliver food and aid packages.³¹ In Japan,

²⁴ Pawluczuk-Bucko, P., *The impact of the pandemic on economic crime*, Białostockie Studia Prawnicze, 2021, Vol. 26, No. 6, p. 81.

²⁵ Dellasega, M.; Vorrath, J. A., *Gangster's Paradise? Transnational Organised Crime in the Covid-19 Pandemic*, SWP Comment 66, December 2020, p. 1.

²⁶ Muggah, R., *op. cit.*, note 23.

²⁷ Cosa Nostra, N'drangheta, Camorra, Sacra Corona Unita, Yakuza, Chinese Triads, Russian Mafia, Sun Yee On.

²⁸ Dellasega, M.; Vorrath, J. A., *op. cit.*, note 25, p. 2.

²⁹ Muggah, R., *op. cit.*, note 23. The Jalisco New Generation Cartel forced pharmacies to buy counterfeit drugs. It is believed that they earn at least 666.5 million dollars a year from the sale of counterfeit drugs. Torres, A., *Mexican cartel, whose leader is the DEA's no. 1 target, 'forces pharmacies to purchase bootleg medicine' - with six out of every ten pharmaceutical drugs sold in the country now counterfeit*, DailyMail.com, 19 March 2020, [<https://www.dailymail.co.uk/news/article-8131247/Deadly-Mexican-cartel-forces>], Accessed 13 March 2024.

³⁰ Gomez T. C., *Organised Crime Governance in Times of Pandemic: The Impact of COVID-19 on Gangs and Drug Cartels in Colombia and Mexico*, Bulletin of Latin American Research, Vol. 39, Iss. S1, 2020, p. 12.

³¹ Keyser, Z., Reuters, April 21, 2020, The Jerusalem Post. In the first months of the pandemic members of rival gangs in Cape Town joined for example to distribute food and essentials packets. According to Aziani, A.; Bertoni, A. G.; Jofre, M.; Riccardi, M., *COVID-19 and Organized Crime: Strategies em-*

newer criminal groups known as “hangura” fought with older “yakuza” groups for profits from the sale of medical supplies³² while criminal group Yamaguchi-Gumi in Yokohama supplied the population with disinfectants, food and economic aid.³³

Organized crime had very quickly recognized the significance and use of the Internet as the main means of distribution of counterfeit medicines offering a wide base of consumers and limited risk of detection. Dark web enabled anonymous transactions among manufacturers, distributors and consumers, offering flexible and decentralized network with liberal access to the online market which strongly supported illegal trade.³⁴ Advanced digitalization increased potential for cyber-crime e.g. online fraud, and higher profits.³⁵ Moreover, in developed countries the Internet was the only way counterfeit medicines could enter the market. Internet sales in counterfeit medicines since the end of the last century is linked to online pharmacies, that is, retail pharmacies which partially or entirely do business via the Internet (mostly on social media platforms and applications for exchanging messages) and which deliver to buyers’ door. There are three main types of e-pharmacies: legal online pharmacy, fake online pharmacy and illegal e-pharmacy. Legal e-pharmacies respect the country’s legal framework in which established, fake e-pharmacies on the surface just sell medicines but in reality, they are fraudulent and steal identity and clone credit cards while illegal online pharmacies are the main system whereby counterfeit medicines can be sold to western markets.³⁶ Thus company Pharmacom International Corporation which manages an Internet pharmacy www.buymeds.com (now hidden) and 18 other related websites asked buyers purchasing script only medicines to register with one of the websites, to make up a short questionnaire about their state of health and give their credit card

ployed by criminal groups to increase their profits and power in the first months of the pandemic, in Trends in Organized Crime, 2023, 26, p. 124.

³² Cerantola, A., *Japanese Gangs Vie for Power Amid Pandemic*, 2020.

³³ Aziani, A.; Bertoni, A. G.; Jofre, M.; Riccardi, M., *op. cit.*, note 31, p. 127.

³⁴ Khan, D.; Rafiqi, F. A., *E-Pharmacies & Fake Medicines: Threat to Public Health*, Indian Journal of Law and Legal Research, 2022-2023, 4, p. 2. According to WHO 50% of medicines are purchased on websites showing their physical address according to the studies carried out by European Federation for Accessing safe medicines 62% of medicines bought over the Internet are counterfeit (50% according to WHO-u). Przysta E., *op. cit.*, note 6, p. 19.

³⁵ Dellasega, M.; Vorrath, J. A., *op. cit.*, note 25, p. 2.

³⁶ According to Lavorgna, A., *The online trade in counterfeit pharmaceuticals: new criminal opportunities, trends and challenges*, European Journal of Criminology, 2015, Vol. 12, No. 2, p. 233. Fake and illegal e-pharmacies are promoted by spam messages, very powerful instruments which have become one of the favorite tools of organized groups for advertising their illegal products, which reach a large number of addresses worldwide and is even adapted to the needs of certain geographical regions. Negri, S., *op. cit.*, note 22, p. 358.

details without any medical documentation being necessary.³⁷ In the virtual illegal trade of counterfeit medicines, there is trade taking place on superficial websites accessible via standard search engines (e.g. Google), and the sale on deep web (a hidden part of the Internet not accessible by conventional web browsers, which can be reached, for example, by special software like Tor browse engine).³⁸ This complexity and internationality of Internet sales is an indicator that virtual crime is operated precisely by organized criminal networks with a significant degree of sophistication.³⁹ Internet is a new powerful instrument which organized crime uses as an important channel to offer counterfeit medicines at both wholesale and retail level, creating independent distribution processes which directly aim at distributors and finally consumers.⁴⁰

4. *MODUS OPERANDI* OF CRIMINAL NETWORKS FOR COUNTERFEITING MEDICAL PRODUCTS

The methods of infiltration of organized crime into the market of pharmaceutical products are varied, because they depend on the complexity of global supply chains. In the counterfeiting of medicines and medical equipment process there are three phases: production, transport, and distribution. Counterfeit products are most often produced in one, transported in the second and distributed to consumers in a third country. In all phases, counterfeiters „maximize fragmentation “in order to escape being uncovered, for example, they separate production from packaging (counterfeit goods are produced in one and packaged in another country)⁴¹. The so called *broken load technique* is used (counterfeit products are directed to the final destination transiting through one or more countries not considered to be countries which produce counterfeits in that area, by which the counterfeiters hope that customs will focus on which country the product has come from and not from which country it originated).⁴² Criminal organizations

³⁷ According to Lavorgna, A., *op. cit.*, note 36, p. 233.

³⁸ *Ibid.*, p. 233. The part of the Deep Web where the illegal sale of goods takes place, also weapons, child pornography, etc. is called the Darknet.

³⁹ *Ibid.*, p. 228.

⁴⁰ Khan, D.; Rafiqi, F. A., *op. cit.*, note 34, p. 7.

⁴¹ Packing counterfeit medicines is identical to the packaging of authentic ones due to the easy access of high quality and cheap printing systems mass production. Przynsya E., *op. cit.*, note 6, p. 16. In Croatian pharmacies fake home antigen tests appeared for speedy detection of the coronavirus so that some distributors of pharmaceutical products actually delivered to pharmacies professional tests, repackaging original packaging several professional tests in individually and declaring them as so-called self-tests, even though there was a difference in collection of swabs. See Uzinić, S., *U prodaji su lažni brzi kućni testovi*, Slobodna Dalmacija, 25 May 2021.

⁴² Przynsya E., *op. cit.*, note 6, p. 26.

use all available forms of transport, even travelers themselves can carry counterfeit medicines as a so-called “mule” in the narcotics trade. Traces are covered, especially in container transport, by storing in free trade zones and warehouses totally unrelated to country-of-origin, reloading products on different means of transport so that only the declared country of origin remains on the goods.⁴³ The distribution strategy depends on the regional surroundings, implementation of control and success in combating counterfeit pharmaceuticals. Products are often distributed through various fake companies, and also directly in the main chain of distribution within legal economic networks via well-known companies or in certain countries, in street markets or via the Internet.⁴⁴ In this „labyrinth“ of the channels transnational criminal networks, apart from founding new companies in various countries which are just „facades“ for their criminal organization, they also bring in legal companies into their „business“. Although counterfeiters often use blackmail and intimidation of retailers, criminal groups try to penetrate the legal distribution system as true distributors. By ordering counterfeit medicines and equipment legal wholesalers and retailers provide organized crime groups the power and capacity to penetrate into a legal supply chain.⁴⁵ With the outbreak of the COVID-19 pandemic it is precisely wholesale distribution of pharmaceutical products that showed how it is „most sensitive to criminal infiltration“.⁴⁶ Then all criminal associations were able to extract profit with a range of activities, from illegal ones, such as production of counterfeit products, to legal ones, for example founding completely legal companies.⁴⁷ Counterfeit networks have the capacity for producing false certificates on the quality (e.g. fake CE labels) and/or other fake official documents enabled them to infiltrate into legal wholesale or distribution networks. There is a range of examples illustrating the infiltration of organized criminal networks into legal markets and economies and fraudulently entering legal entities in this area.

An earlier case involved an English accountant and pharmaceutical distributor who managed a company with headquarters in Luxembourg and from December 2006 to May 2007 imported 72.000 packets of counterfeit medicines, that is, over two million doses (of which a third were medicines for serious illnesses such as prostate cancer, heart problems and schizophrenia). His company imported medicines to the value of 1.4 million GBP, while their retail value was 4.7 million GBP,

⁴³ *Ibid.*, p. 16.

⁴⁴ *Ibid.*, p. 16.

⁴⁵ *Counterfeit Medicines and Organised Crime*, *op. cit.*, note 20, p. 93.

⁴⁶ Aziani, A.; Bertoni, A. G.; Jofre, M.; Riccardi, M., *op. cit.*, note 31, p. 129.

⁴⁷ Smith, D. C., *Paragons, pariahs, and pirates: A spectrum-based theory of enterprise*, *Crime Delinq*, 1980, Vol. 26, No. 3, pp. 358–386, According to *Ibid.*, p. 126.

so they gained a profit of 3 million GBP. Counterfeit medicines were transported by sea from China through Hong Kong, Singapore and Belgium, after which they were packed into French medicines which were sold in Great Britain. It was the first bigger case in which counterfeiters used the technique so called parallel distribution, and which fraudulently sold to pharmacies or hospitals 25,000 packets of counterfeit „medicines“ containing only 50 to 80% of active ingredients plus impurities of an unknown nature. The perpetrator with partners used the defense that French medicines had been imported from Brussels and that „parallel trading“ had been legally practiced, but Chinese was written on the boxes, and they had bought machines to make the labels in French to show that the medicines were from France.⁴⁸ Seizure of the packets with counterfeit medicines which were sent from the Netherlands to the United Kingdom uncovered an illegal wholesale business of Dutch suspects who had received medicines from wholesalers from Pakistan and sold them to consumers, suppliers, re-sellers and middlemen and sent to addresses in Holland, Belgium, Germany Denmark and the USA. Packets were sent and received via various mailboxes in various parts of town, and buyers had to make payment to a certain bank account while cash could be sent to various mailboxes.⁴⁹ A more recent case of fraud, with money laundering, is in the procurement of 10 million protective face masks valued at 15 million Euros. German Healthcare was tricked when they contracted with two companies in Switzerland and Germany via cloned websites of a legal company in Spain.⁵⁰ Furthermore, the company with headquarters in Faenza dealing with sale of paramedic equipment, imported from China in 2020 surgical masks, FFP2 masks⁵¹ protective clothing and glasses, face guards and footwear for tens of millions of Euros free of import fees and VAT, the exemption of which depended on direct delivery exempt from fees to public health institutions in order to combat the pandemic. However, the company placed the goods with another private company which was its mother company, for a higher price and with the falsified documents.⁵² A particular way of defrauding exists in e-shopping so in Italy falsified prescription medicines were

⁴⁸ See Przyswa E., *op. cit.*, note 6, p. 37.

⁴⁹ Hall, A.; Koenraad, R.; Antonopoulos, G., *op. cit.*, note 9, p. 304.

⁵⁰ According to Interpol, frauds in 2020 were organized by criminal groups who orchestrated a complex delivery chains among suppliers in Spain, Ireland and Holland. Also, the well-known case of embezzlement of Italian funds where packets of economic aid for COVID-19 to the value of 45.000 euros was given to a member of 'Ndranghete via a complex scheme of tax fraud, fake invoices and names within the sale of steel sector. See Aziani, A.; Bertoni, A. G.; Jofre, M.; Riccardi, M., *op. cit.*, note 31, p. 126 and Sokanović, L.; Roksandić, S.; Stošić, I., *op. cit.*, note 10, p. 78.

⁵¹ Medical masks FFP2 sold to the Emiliji-Romagni hospital were not certificated nor pursuant to penetration parameters of materials for filtration. V. Sokanović, L., *Krivotvorenje medicinskih proizvoda u vrijeme pandemije: nova tržišta kriminalnih skupina*, Liječničke novine, No.. 208, April 2022, p. 45.

⁵² Sokanović, L.; Roksandić, S.; Stošić, I., *op. cit.*, note 10, p. 81.

sold by an Internet pharmacy which pretended to have its physical address in the United Kingdom. The criminal network, led by a citizen of India, was located in Switzerland, while the servers were in Canada and the USA. Managing the supply chain functioned by drop-shippers, i.e., people storing articles ready for sending, and who were located in various European countries in order to escape customs inspection, so that for example packages were sent to Italy from Germany while Internet financial operations were carried out in Eastern Europe.⁵³ Also, an online pharmacy had a Swiss number as a call center for offering medical advice, but calls were answered by six men (four Italians and two French) who carried out criminal activities from a warehouse in Northern Italy.⁵⁴ Therefore, cybercriminals pretended they were surgical companies, even medical institutions and the real pandemic, due to digital transformations in healthcare, created the expression „cyber pandemic“.⁵⁵ The Internet enables complex criminal activities without time and spatial limitations even for smaller groups which otherwise do not have the organizational or financial capacity. Apart from producing fake medicines, organized criminal groups also steal authentic medicines by repackaging them and changing the expiry date thereby selling them again.⁵⁶ During the pandemic the number of various thefts of all goods related to the outbreak increased.⁵⁷

The *modus operandi* of organized crime is also an abuse of public funds by taking advantage of national and international aid in big health crises access to public funds which were increased during the pandemic and more speedily paid out, enabled them to infiltrate into the legal economy and increase profits⁵⁸ Market globalization has influenced traditionally local or regional criminal groups to expand

⁵³ Lavorgna, A., *op. cit.*, note 36, p. 233.

⁵⁴ Medicines in the warehouse worth 3 million euros were confiscated. *Ibid.*, p. 236.

⁵⁵ Pawluczuk-Bucko, P., *op. cit.*, note 24, p. 77. Illegal online pharmacies are linked to organized crime networks that use unwanted e-mail, spam, viruses/malware/spyware and other cyber security threats that include financial fraud and data theft. Mackey, K. T., Nayyar, G., *Digital danger: a review of the global public health, patient safety and cybersecurity threats posed by illicit online pharmacies*, British Medical Bulletin, 2016, 118, p. 123.

⁵⁶ See more Riccardi, M.; Dugato M.; Polizzotti, M.; Pecile, V., *The theft of medicines from Italian hospitals*, Transcrime Research in Brief - N.2/2015, Trento. About the theft of the medicine Herceptin from a delivery truck to Italian hospitals and Operation Volcano see more in Kohli, V. P., *Combating Falsification and Counterfeiting of Medicinal Products in the European Union – A Legal Analysis*, Copenhagen, 2018, pp. 109-118.

⁵⁷ So were millions of protective masks from airport storage in Kenya protective gloves to the total value of a million dollars from a container in Florida stolen and 200 respirators directed to Columbia while in England during the shortages 150.000 rolls of toilet paper were stolen. See Bešker, I., *Organizirani kriminalni okretaji se najtraženijoj robi: 'Ovo je sigurnosni izazov generacije'*, Jutarnji list, 4 March 2021., [<https://www.jutarnji.hr/vijesti/svijet/organizirani-kriminal/>], Accessed 25 February 2024.

⁵⁸ For example, European aid such as Recovery Fund. According to Dellasega, M.; Vorrath, J. A., *op. cit.*, note 25, p. 6.

their operations by creating links with other criminal groups in other regions. Research showed that the production centers are mainly located in South Asia (India and Pakistan), China, Hong Kong, Russia and Latin America, and distribution is in parts of the Middle East, Africa and Central Europe. Transit countries between producers and consumers are Spain, Hungary, Great Britain and the Netherlands where packages are diverted with a higher degree of “legitimacy” for markets in the US and Western Europe.⁵⁹

5. INTERNATIONAL AND NATIONAL LEGAL FRAMEWORKS FOR COMBATTING COUNTERFEIT MEDICINES AND MEDICAL PRODUCTS

Besides the lack of universally acceptable definitions as well as the conflict between the right to public health and intellectual property rights, the increase in the number of fake medicines in both legal and illegal supply chains has led to the establishment of legal frameworks for punishing. Given that the sale of falsified medical products is considered to be in an alarming category of transnational crime for all countries of the most importance of the UN Convention against Transnational Organized Crime (PALERMO convention)⁶⁰ which is also applicable to organized criminal groups active in this area.⁶¹ From the criminal law perspective, an important instrument is the Convention of the Council of Europe on the counterfeiting of medical products and similar crimes involving threats to public health (MEDICRIME convention).⁶² This criminal law convention forms the foundation for international and national cooperation of judicial and health powers with the aim of protecting all people, particularly the most vulnerable, patients,⁶³ because it contains incrimination descriptions in art. 5-9 on manufac-

⁵⁹ Hall, A.; Koenraad, R., Antonopoulos, G., *op. cit.*, note 9, p. 303.

⁶⁰ Official Gazette, International treaties, No. 14/2002.

⁶¹ Art. 2a A »*Organized criminal group*« is a structured group of three or more persons, which exists for a certain amount of time and acts in agreement with the aim of committing one or more criminal acts or criminal acts determined on the basis of this Convention, in the aim of directly or indirectly acquiring financial or some other material benefit; art. 2c A »*Structured group*« is a group which is gathered not by chance to directly commit a criminal offense, and which does not need to have to have formally established roles, durability of membership or developed structure.

⁶² Official Gazette, International treaties, No. 7/2019. Also art. 13 of the Directive 2011/62/EU on counterfeit medical products by the European Parliament and Council of 8 June 2011 on amendments to Directive 2001/83/EZ on the Community Code applicable to medicines for human consumption, in the aim of preventing the entry of falsified medicines in legal supply chain, SL L 174, 1 September 2011. See more Valverde, J. L., *Illegal medicines as threats to public health*, Pharmaceuticals Policy and Law 19, 2017, p. 5.

⁶³ Alarcon-Jimenez, O., *The Medicrime Convention-fighting against counterfeit medicine*, Eurohealth International, Vol. 21, No. 4, 2015, p. 26.

turing, supply and sale of counterfeit medical products as well as punishing abetting, aiding and attempting these criminal activities.⁶⁴ An important provision in combating organized crime in this area is regulating aggravating circumstances if the act is committed within a criminal organization (art. 13e). MEDICRIME convention also contains a very important provision on corporate liability (art. 11) the aim of which is to make legal entities liable for counterfeiting products done in their name and for their benefit by anyone in a managerial position within their powers, as well as for misdemeanors committed by any employee or subject agent whenever anyone in a leading position committed omissions in inspection (did not undertake appropriate and reasonable steps to prevent employees and agents from participating in criminal activity in the subject's name).⁶⁵ A regional instrument enabling the fight against counterfeiting is also the Council of Europe Cybercrime Convention.⁶⁶

On the basis of the above-mentioned conventions numerous organizations and agencies have been effective in combating medicinal counterfeiting: World Intellectual Property Organization, World Trade Organization, Interpol, Europol, Olaf, EUIPO, etc.⁶⁷ A number of actions by international bodies have been undertaken in order to uncover and combat counterfeiting,⁶⁸ but, globally most significant are those undertaken by Interpol under the name of Pangea, implemented since 2008. At the very beginning of the COVID-19 pandemic due to the danger of infectiousness, Interpol in March 2020 carried out *Pharmaceutical crime operations* under the name of Pangea XIII in which the police, customs and health bodies of 91 countries participated with the aim of reducing illegal Internet sales of counterfeit medicines and medical equipment.⁶⁹ Operation Pangea XIV in May 2021 showed that criminals continued to profit on the demand for personal protection and hygiene products, brought about by the COVID-19 pandemic. Fake COVID-19 tests made up more than half of all seized medical products, resulting

⁶⁴ The expression “counterfeit” is really a synonym for a “falsified”. The Convention is applicable to medical products regardless of their status pursuant to intellectual property regulations which means it covers generic medicines and that the protection of intellectual property rights is not within that scope. Negri, S., *op. cit.*, note 22, p. 360.

⁶⁵ *Ibid.*, p. 362.

⁶⁶ Official Gazette, International treaties, No. 9/2002.

⁶⁷ In the fight against counterfeit private non-profit organizations are also included such as Global Anti-Counterfeiting Network and Commercial Crime Services-Counterfeiting Intelligence Bureau. Nelson, M.; Chang, D., *op. cit.*, note 8, p. 1099.

⁶⁸ See more Sokanović, L.; Roksandić, S.; Stošić, I., *op. cit.*, note 10, pp. 77-82.

⁶⁹ This joint action led to the arrest of 121 people, seizure of disinfectants, surgical masks, sets for COVID-19 testing, various vaccines and antimalaria and antiviral medicines in the total value of 14 million USD and the removal of more than 2500 websites (Internet links, social networks and advertisers). See Kurtović Mišić, A.; Sokanović, L.; Mišić Radanović, N., *op. cit.*, note 2, p. 427.

in 277 arrests around the world, seizure of potentially dangerous medicines to the value of more than 23 million USD and the removal of over 113 thousand Internet websites. In Italy more than 500.000 fake surgical masks were found as well as 35 industrial machines used for the production and packaging of counterfeits.⁷⁰ In the operation called Pangea XV in which 94 countries were included, Interpol in 2022 seized more than 3 million units of doping substances and narcotics, including more than 7800 illegal and counterfeit medicines and medical products. Counterfeit medicines are mostly produced in Asian countries and counterfeit stimulants for erectile dysfunction originate from India. More than 4000 websites have been removed containing advertising for illicit products. Almost 3000 packets have been checked as well as 280 postal hubs in airports at borders and postal or cargo mail distribution centers and more than 600 investigations initiated and more than 200 searches. The most significant action of Pangea XV was to stop the activities of at least 36 organized criminal groups. The last operation of Pangea XVI carried out in 89 countries in October 2023 resulted in 72 arrests and 325 investigations for seizing medical products valued at up to 7 million USD and the removal of 1300 websites.⁷¹ Europol's latest undertaking called SHIELD IV (2023) implemented in 30 countries including Croatia resulted in 296 arrests, 1284 persons being charged, investigations into 52 organized criminal groups, removal of 92 websites and seizure of hundreds of thousands of packages of counterfeit medicines with over 12 million tablets and pills, ampoules, raw and doping substances, overall value of 64 million Euros.⁷² In breaking criminal groups infiltrated in the legal market, the European Office for combating fraud (OLAF) has an important role and up till May 2020 has already identified more than 340 companies mediating or sellers with falsified or poor quality products linked to the COVID-19 pandemic.⁷³

Ratification of the MEDICRIME convention resulted in the implementation of rules on criminal liability for counterfeiting medical products in Croatian criminal legislation. Croatian Criminal Code⁷⁴ (hereinafter: CCC) proscribes in art. 185 the act of counterfeiting medicines or medical products which maybe committed by various producers and suppliers. The fundamental form of the act is producing the fake medicine, active substance, auxiliary substance, medical prod-

⁷⁰ Available on:
[<https://www.interpol.int/Crime>], Accessed 15 March 2024.

⁷¹ *Ibid.*

⁷² Available on:
[<https://europol.europa.eu>], Accessed 15 March 2024.

⁷³ OLAF, Press Release No 16/2020.

⁷⁴ Official Gazette No. 125/11, 144/12, 56/15, 61/15, 101/17, 118/18, 126/19, 84/21, 114/22, 114/23, 36/24.

uct, its constitutive parts or utensils, or the real medicine is changed, its active substance, auxiliary substance or medical product, its constituent parts or utensils. The prescribed punishment is from six months or up to 5 years in prison. The same punishment is for persons procuring or offering to procure, store, import or export, offer for sale whether as if original, falsified or changed medicine, active substance, auxiliary substance, medical product, its constitutive parts or accessories (sec. 2). The most serious act for which a prison sentence from one to eight years is prescribed is for the person who betrays the trust they have as an expert, producer or supplier or who commits the act via means suitable for mass distribution such as informational systems including the Internet (sec. 5).⁷⁵ The act is blanket in nature and represents a formal criminal act because finishing the act does not demand creation of consequences in the form of destroying health or the death of one or more persons.⁷⁶ An important element of the act is the perpetrator's intention (*dolus*) about the production of the falsified medicine or changing the real medicine.⁷⁷ The definition of a falsified medicine is regulated in Medicines Act⁷⁸ while the concept of a medical product is determined Medical Products Act.⁷⁹ The MEDICRIME convention in article 11 requires governments to regulate the liability of legal entities in case that an individual commits the act for the benefit of the legal entity being in a superior position acting independently or as a part of the body of a legal entity on the base of: a) authority to represent that legal entity; b) authority to make decisions on behalf of that legal entity; c) authority to monitor and supervise within the legal entity.⁸⁰ Croatian criminal legislation

⁷⁵ Making fake or changing original internal or external packaging of a medicine or medical product, the summary of contents, description of medicine, directions for usage, documentation on active or auxiliary substances is punishable by prison sentence of up to 3 years (art. 185 sec. 3). Attempting a criminal act is punishable and the products and means of manufacture will be mandatorily seized.

⁷⁶ The act will be commensurate with acts against life and body or with the criminal act of unconscientious treatment (art. 181 CCC) or with the criminal act of spreading and transmitting infectious diseases (art. 180 CCC). Sokanović, L.; Roksandić, S.; Stošić, I., *op. cit.*, note 10, p. 76.

⁷⁷ Pavlović, Š., *Kazneni zakon*, Rijeka, 2015, p. 863. According to some authors, the possibility of negligence is not completely excluded for the criminal acts contained in the MEDICRIME Convention. See Novaković, F., *Substantive Criminal Law of the Medicrime Convention and the Criminal Legislature of Bosnia and Herzegovina, The Ratio of Harmony and Disharmony*, Journal of the Bar Association of Vojvodina, 3, 2023, p. 1045.

⁷⁸ Art. 3. section 1. t. 49., Official Gazette, No. 76/13, 90/14, 100/18.

⁷⁹ Art. 3. t. 1.

⁸⁰ This relates to cases in which the legal entity can be responsible when the lack of supervision or control on the part of stated physical persons enabled commission of the criminal act established pursuant to the convention on benefit of the legal entity. See more Mišić Radanović, N., *The liability of legal entities for criminal acts in Croatian court practice*, 36th International Scientific Conference on Economic and Social Development – “Building Resilient Society”, 2018. pp. 225.-235. and Sabia, R., *Prosecuting corporations for international crimes: in search of new perspectives?* RIDP, Vol. 93, No. 1, 2022, pp. 209-229.

regulates that the perpetrators of the criminal act of counterfeiting medicines or medical products can also be legal entities such as manufacturers and suppliers of medicines and medical products⁸¹ and that participants in Internet sales (distance) of medicines issued without a recipe.⁸² Special rules for criminal liability of legal companies in the Republic of Croatia are regulated by Law on Liability of Legal Persons for Criminal Offenses⁸³ while the PALERMO convention is implemented in the provisions of CCC on the liability of criminal organizations. Provisions art. 328 and 329 CCC provide for liability for organizing leading or committing a criminal act within such a criminal association. A criminal association is made up of a minimum of three persons colluding with the common aim of one or more criminal acts, for which they can be sentenced to prison for 3 or more years which does not include the association of persons by chance linked to directly committing a criminal act.⁸⁴ Art. 329. sec. 1. CCC prescribes a more serious punishment for persons who aware of the criminal aim of the association or its criminal activity commit a criminal act within such an association or incite another to commit a criminal act within such an association.⁸⁵ Therefore, the Republic of Croatia has the legal instruments to combat organized criminal networks active in the area of counterfeiting medical products and which enable prosecution of legal entities which are just a cover for organized crime and only at first glance function pursuant to regulations, but in the background commit crimes.⁸⁶

6. DIFFICULTIES IN DETECTING AND PROSECUTING COUNTERFEITERS' CRIMINAL NETWORKS

Counterfeiting is very profitable, but a very low risk criminal activity, because uncovering is difficult for a number of reasons. Criminal organizations are difficult to identify, especially if linked to „white collar“ crime and are infiltrated into the legal environment. Counterfeiting any kind of good is organized as a complex and coordinated network of several criminals who undertake constant and long-lasting illegal activities. A counterfeiter whose *modus operandi* is that

⁸¹ Art. 135. sec. 1. of the Medicines Act., Official Gazette, No. 76/13, 90/14, 100/18.

⁸² Art. 136 sec. 1. of the Medicines Act. In the aim of protecting consumers from counterfeit medicines a common logo has been introduced for Internet pharmacies in the European Union. Bilić Paulić, M., *op. cit.*, note 2.

⁸³ Official Gazette No. 151/03, 110/07, 45/11, 143/12, 114/22, 114/23.

⁸⁴ Art. 328. sec. 4. Croatian Criminal Code.

⁸⁵ According to sec. 2. of this article, aider and abetter can be punished more lightly.

⁸⁶ On possibilities of widening the application of the theoretical concept and legal figure of the organized power apparatus see Vuletić, I., *Dometi koncepta "organiziranog aparata moći"*, Hrvatski ljetopis za kazneno pravo i praksu, vol. 21, 1, 2014, pp. 23-38, and Novoselec, P.; Martinović, I., *Komentar Kaznenog zakona, I. knjiga: Opći dio*, Zagreb, 2019, p. 277.

a large number of little packages are sent from one EU member state to another EU member state is very difficult to uncover and stop.⁸⁷ Investigations are made more difficult in all systems of decentralized factories such as for example Chinese, as it involves a complex labyrinth with innumerable middlemen and suppliers.⁸⁸ The use of the Internet modifies the organizational level of the criminal network so that newcomers are enabling to join the chain of counterfeits as local or even international retailers, which facilitates relations among perpetrators and their contact with clients.⁸⁹ The illegal sale of medical products via Internet sites is difficult to detect because it is often the result of fraud by manipulating websites. Difficulties in revealing counterfeit medicines lie in finding out where and when sub networks can be incorporated with each other or even mutate so that various groups are included, from Chinese manufacturers, smugglers, wholesalers from the pharmaceutical sector, corrupted customs officers, Chinese or Russian soldiers, cyber criminals, „white collar“ criminals, mafias and so on.⁹⁰ Internationalization of illegal networks together with the decentralization of operative cells has led to the widening of criminal activity.⁹¹ Due to so-called delocalization, it is difficult to identify criminal organizations while their close connections make them transnational networks. However, empirical data in some research show that the networks and participants involved in trade are very flexible and complex structures existing in both permissible and non-permissible categories, online and offline, both global and local. The operation of the supply of non-allowable medicines mostly differentiates in the sense of size, scope, organization and legality.⁹² Organization of counterfeiting can be described as “individual’s puzzle”, members of closely connected groups, family and friends working as teams located in various geographical locations. This smuggling network includes various individuals or teams in close contact who play various roles from managing warehouse and packaging units, redirecting posted packets, transport, right up to maintaining informational services used for online advertising and sales and managing companies used as fronts for something else.⁹³

Organized criminal groups also use different usual violent methods of extortion, intimidation, blackmail, and violence against public officials in charge of detection.⁹⁴

⁸⁷ Sokanović, L., *op. cit.*, note 51, p. 46.

⁸⁸ Przyswa E., *op. cit.*, note 6, p. 51.

⁸⁹ Lavorgna, A., *op. cit.*, note 36, p. 228.

⁹⁰ Przyswa E., *op. cit.*, note 6, p. 77.

⁹¹ *Counterfeit Medicines and Organised Crime*, *op. cit.* note 20, p. 89.

⁹² Hall, A.; Koenraad, R.; Antonopoulos, G., *op. cit.*, note 9, p. 296.

⁹³ *Ibid.*, p. 309.

⁹⁴ Example, attacks on director of Nigerian National Agency for Food and Drugs Administration and Control. Cit. *Counterfeit Medicines and Organised Crime*, *op. cit.* note 20,

Victims of counterfeiting probably will not suspect that they are using fake medicines. Packaging is quickly thrown away, and medicines cannot be detected in the bloodstream after a few days and “the evidence is destroyed as soon as it is swallowed or injected.” Not even the very victims who, for the most part, are not even aware of the risks of on-line shopping do not want to reveal that they bought medicines without a prescription via the Internet.⁹⁵ Moreover, there is a lack of public awareness about counterfeit medical products⁹⁶ and it is believed that illegal medicines are crimes without victims.⁹⁷ One of the reasons is payment by cash to avoid banking systems by virtual currencies such as Bitcoin. Thereby, following money traces is made more difficult, particularly if cyber money laundering of huge amounts of money atomizes, that is, change into so called. *micro dust* so that money is quickly transferred through thousands electronic transactions.⁹⁸ Also, organized crime has a lot of capital for corruption of state and local entities, eg. for bribing customs officers at border controls. Finally, listed as factors impeding the fight against counterfeiting medical products are a lack of or deficiency in normative national regulation on the production of medicines and distribution, mechanisms for implementing regulations, insufficient international cooperation and mild penalties for counterfeiting.⁹⁹

7. SOCIAL, ECONOMIC, AND POLITICAL CONSEQUENCES OF PROFIT ACQUIRED BY COUNTERFEITING MEDICAL PRODUCTS

The danger of organized crime in the area of counterfeit medical products emerges from its far reaching social, political, and economic consequences. Harmful consequences are reflected in the violation of Fundamental Human Rights - right to life, right to health, quality and trust in the health system and in the grave danger to global and national security. Counterfeiting medicines, vaccines and other medical products also lead to fatal consequences, because some fake medicines contain lead, arsenic, rat poison or cement.¹⁰⁰ Organized crime immanently widens the scope of its influence and power precisely in times of social crisis whereby it gains the political support of local communities and widens its influence to central powers. This was evident during the COVID-19 pandemic in organized criminal groups offering to

⁹⁵ Blackstone, A. E.; Fuhr, P. J. Jr.; Pociask, S., *op. cit.*, note 11, p. 220.

⁹⁶ Slak, B.; Frangež, D., *Detection and Investigation of Counterfeit Medical Products in Slovenia*, Kriminologijos studijos, 2022, Vol. 10, pp. 8-29.

⁹⁷ See more Valverde, J. L., *op. cit.*, note 62, p. 8.

⁹⁸ See Pavlović Š., *Komentar Zakona o sprječavanju pranja novca i financiranja terorizma*, Rijeka, 2018, p. 553.

⁹⁹ More about profitability, low risk of detection and light penalties in *OECD/EUIPO Trade in Counterfeit Pharmaceutical Products, Illicit Trade*, 2020, pp. 52-56.

¹⁰⁰ Pawluczuk-Bucko, P., *op. cit.*, note 24.

help those at risk and in need.¹⁰¹ Thus in Japan after declaring a state of emergency Yakuze immediately sent help, and in their attempt that the Japanese government saw them as a legitimate speaker offered to disinfect the Diamond Princess cruiser, blocked in the Yokohama.¹⁰² At the same time, Mexican drug traffickers published pictures of packets being distributed of food with their logo or sticker while other narco-cartels posted online videotapes in which their members were handing out food parcels.¹⁰³ Thus, the pandemic certainly strengthened the social influence of organized crime in the public sphere.¹⁰⁴ This well-known “Robin Hood myth” increases the power and social acceptance of gangs and narco-cartels, assisting them to include civil society and government in supporting their criminal operations.¹⁰⁵

Times of economic crisis and disorders in economic functioning are significant criminogenic factors, so the economic consequences are linked to the so called parallel economy (gray and black zones) in which organized crime invests criminal money in legal economic entities, for example, buying companies, restaurants and hotels whose owners are at risk of bankruptcy or financial difficulties.¹⁰⁶ Such infiltrations of accumulated profits violate market rules and since counterfeiters do not pay taxes or import/export duties, states have less income, all of which slows down economic growth.¹⁰⁷ The black market of counterfeiting is an underground economy characterized by tax evasion. The consequences of counterfeiting are the violation of intellectual property rights, non-compliance with basic standards of health safety and product quality,¹⁰⁸ and the victims of counterfeiting, in addition to patients and consumers, are also the pharmaceutical industry.

¹⁰¹ In Southern Italy, the shaken economy in battling the coronavirus was a vacuum for organized crime. D’Ignoti, S., *Mafia, Poverty, and the Pandemic*, 2020.

¹⁰² Aziani, A.; Bertoni, A. G.; Jofre, M.; Riccardi, *op. cit.*, note 31, p. 128.

¹⁰³ Example, Cártel del Golfo printed the ‘CDG’ logo on aid packets or sealed them with stickers on which was written: “Gulf Cartel, in support of Ciudad Victoria, Mr. 46, Vaquero” and Mr. 46 is pseudonym of the leader of the Cártel del Golfo group. *Ibid.*, p. 125.

¹⁰⁴ In the same way the Italian mafia and Japanese yakuze strengthen after the First World War. Muggah, R., *op. cit.*, note 23.

¹⁰⁵ Gomez, T. C., *op. cit.*, note 30, p. 13.

¹⁰⁶ Pawluczuk-Bucko, P., *op. cit.*, note 24, p.78. Economic areas which are vulnerable due to financial difficulty are tourism, hospitality, transport, esthetic services, art and entertainment and recreation. According to Aziani, A.; Bertoni, A. G.; Jofre, M.; Riccardi, M., *op. cit.*, note 31, p. 129.

¹⁰⁷ Nelson, M.; Chang, D., *op. cit.*, note 8, p. 1072. Al Capone, who was convicted of tax evasion in 1931, discovered that the statement “They can’t collect legal taxes from illegal money” was wrong. Available on [<https://www.forbes.com/sites/kellyphillipsrb/2018/10/17/>].

¹⁰⁸ Nelson, M.; Chang, D., *op. cit.*, note 8, p. 1072. and Verfaillie, K.; Beken, T. V., *Proactive policing and the assessment of organized crime*, Policing: An International Journal of Police Strategies & Management, 31(4), 2008, pp. 534-552.

The illegal market for counterfeit pharmaceuticals offers an additional way for criminal groups to launder money and finance other illegal activities.¹⁰⁹ Given the centrality of money laundering in the operations of criminal organizations, it is a task that must be equally central in the fight against organized crime.¹¹⁰ Organized crime gains political support and power through corruption and deals between the political and criminal spheres, i.e. aboveground and underground. For example, political decision makers protect certain criminal groups in exchange for financial support in election campaigns.¹¹¹ Profit gained from organized crime serves to bribe all three branches of government with the aim of enabling criminal activities of organized groups and protection from being uncovered and prosecuted. Furthermore, it is not necessary to specifically prove the close connection between the counterfeiting of all types of goods and the weapon trafficking and terrorism. In addition to financing from legal sources, the activity of terrorist associations¹¹² is financed by the assets gained by the commission of predicate criminal acts.¹¹³ Acquired profit is reinvested in buying weapons which then are sold at higher prices to terrorist organizations, whereby profit increases even more and at the same time finances terrorism. Counterfeiting of medical products is also engaged in by terrorist organizations, for example the Lebanese Hezbollah, which released over 10 tons of dangerous pills for the treatment of sexual disorders on the market and earned hundreds of millions of dollars.¹¹⁴

8. INSTEAD OF A CONCLUSION: SUGGESTIONS *DE LEGE FERENDA*

Given that organized crime is constantly finding and changing the best methods and ways to acquire profit and power, the widespread and fatality of counterfeit medical products on the part of organized criminal association has to worry all of humanity. Regardless of whether it concerns intellectual property crime, cy-

¹⁰⁹ *Counterfeit Medicines and Organised Crime*, *op. cit.* note 20, p. 90. According to the Europol report (EMPACT 2022 – 2025), almost 70% of criminal groups in EU use money laundering.

¹¹⁰ Keatinge, T., *Money Laundering: The Beating Heart of Organised Crime*, 27 November 2023, [<https://rusi.org/explore-our-research/publications/commentary/money-laundering-beating-heart-organised-crime>], Accessed 7 March 2024.

¹¹¹ Dellasega, M.; Vorrath, J. A., *op. cit.*, note 25, p. 6.

¹¹² The terms terrorist and terrorist group or organization are defined in art. 3. of Act on Prevention of Money Laundering and Financing of Terrorism, Official Gazette No. 108/17, 39/19, 151/22.

¹¹³ Pavlović Š., *op. cit.*, note 98, p. 19. Interpol believes that profits from counterfeit medicines goes to terrorist organizations, including Al Qaida. See Attaran, A.; Bate, R.; Kendall, M., *op. cit.*, note 7, p. 4.

¹¹⁴ The terrorist organization Real IRA is also involved in the counterfeiting of medicines. According to Cannon, T. D., *War Through Pharmaceuticals: How Terrorist Organizations Are Turning to Counterfeit Medicine to Fund Their Illicit Activity*, 47 Case W. Res. J. Int'l L. 343, 2015, p. 357.

bercrime, white collar crime, it is about organized crime which is transnational. Due to the connection of criminal networks over various continents, cross-border organized crime can also be called transcontinental. Counterfeiting of medical products is a threat to lives, health and security and economic and social development. Due to its close connection to economic crime, corruption, money laundering, and especially direct and indirect links to terrorism with the proliferation of weapons of mass destruction it is a great risk and threat to global security and world peace. Corruption, money laundering and terrorism destroy every political system. All of the stated crimes really deserve the name of international crime, that is, crimes against the whole international community. Not one state has enough resources and the capacity to defend itself from the problem of complex cross-border operations with many middlepersons organized in well structured, flexible, and operative networks of counterfeiters, especially in the in the virtual world. The efficiency of the prosecution terrorism, corruption and money laundering also depends on the uncovering the falsified medical product as a predicate offense. Therefore, several additional measures could be taken which would intensify the fight against this type of organized crime. In the area of conventions instruments, it would be necessary in the PALERMO convention to establish criminalization of falsifying medical products. Such additional responsibility would ensure extradition or criminal prosecution according to the principle of *aut dedere aut punire* and the principle of universal jurisdiction. At the national level, it is necessary to improve criminal law mechanisms, for example in art. 185 of the CCC, following the French solution, to prescribe more severe punishment if the falsification of medical products is perpetrated by criminal groups. Following the example of the Austrian solution, it would be desirable to introduce stricter punishment into art. 192. CCC as a grievous criminal offense against human health in cases where the counterfeit medicine led to health impairment, serious bodily injury, pregnancy termination or the death of one or more persons. In the fight against illegal profits gained by counterfeiting which then finances terrorism, it would be good if in Art. 265 of the CCC prescribes as a qualified form of money laundering if the perpetrator acts knowing that the money is from a terrorist or a terrorist organization. Also, it is extremely important to intensify the application of the instrument extended confiscation of proceeds of crime from individuals and legal entities participating in an organized chain of counterfeiting medical products.

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