Journal of Indonesian Legal Studies
Vol. 10 Issue 1 (2025) 165-210
DOI: https://doi.org/10.15294/jils.v10i1.3692
Online since: August 31, 2025

Journal of INDONESIAN LEGAL STUDIES
https://journal.unnes.ac.id/journals/jils/index

Illicit Trade in Counterfeit Medicines: Challenges, Solutions, and a Case Study of Indonesia

Khaled Mohammad Khwaileh [a], Ena Kazić-Çakar [b]

[a] Faculty of Law, Jadara University, Jordan
[b] Faculty of law, International University of Sarajevo, Bosnia and Herzegovina

Corresponding email: *kh.khwaileh@jadara.edu.jo*

Abstract

This paper examines the challenges posed by the trafficking of counterfeit medicines, particularly in developing countries affected by conflicts and challenging regimes. Counterfeit medicines imitate legitimate products, posing severe health risks to unsuspecting consumers. Criminal networks thrive in areas with weak regulations, governance, and enforcement capacity, taking advantage of chaos and limited oversight. Factors like corruption, porous borders, and high medicine costs further contribute to the spread of this illegal trade. The role of international organizations, such as the World Trade Organization (WTO), World Health Organization (WHO) and INTERPOL, in combating this crime is highlighted, emphasizing the need to strengthen enforcement efforts and enhance global cooperation. To address this significant global health threat, strict penalties, international collaboration, and prioritizing public health are crucial components of an effective approach. One avenue of change is that the developing countries be allowed to manufacture generic drugs but the World Trade Organization's Agreement on Trade-Related Aspects of

Intellectual Property Rights (TRIPS) and patent protections limits access to affordable medicines, hindering the production of generic drugs in poor countries. By ensuring access to affordable medicines, the international community can protect vulnerable populations and combat the trafficking of counterfeit medicines.

KEYWORDS *Counterfeit Medicines, Developing Countries, TRIPS Agreement, Global Cooperation*

Introduction

Counterfeit medicines are fake or substandard pharmaceutical products that imitate legitimate medicines, resulting in severe health risks and serious consequences for unsuspecting consumers. Counterfeits are always inferior in terms of quality, safety, and efficacy compared to the original pharmaceuticals, and subsequently, they pose an unpredictable risk to public health and lead to loss of confidence in medicines, healthcare providers, and health systems.[1] They may refer to "branded or generic drugs, excipients, active substances, medical supplies, and devices".[2] The World Health Organization categorizes them into falsified (mispresent identity, content, or source), substandard (fail to meet the quality standards or have expired) and unregistered/unlicensed (no evaluation or approval).[3]

The global public has been deeply concerned ever since the statement was made on Monday 29th of January 2024, by the World Health Organization with which the public was warned about global shortages of popular diabetes medicines that are also used for weight loss, named Nova Nordisk-Ozempic, and that shortage has been linked to rising reports of suspected counterfeits.[4]

---

1 Ziavrou, Kalliroi S., Stephen Noguera, and Vassiliki A. Boumba. "Trends in counterfeit drugs and pharmaceuticals before and during COVID-19 pandemic." *Forensic Science International* 338 (2022): 111382.

2 Ziavrou, Noguera, and Boumba.

3 WHO. *Substandard and Falsified Medical Products.* (WHO, 2018). Available online t https://www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products

4 Wingrove, Patrick. "Rise in reports of fake weight-loss drugs linked to shortage of real thing, WHO says", *Reuters,* January 30, 2024. Online at

The warning was clear as the "fake versions of the drugs which belong to a class called GLP-1 agonists, are most often sold and distributed through unregulated outlets including social media platforms and carries serious health risks".[5] It is noteworthy that besides its regular purpose – controlling blood glucose levels and reducing the occurrence of serious health complications related to diabetes (heart attack and stroke),[6] this medicament has been widely used for weight reduction and it is quite popular. According to Hart, "its soaring popularity and strictly limited supply, fostered a growing market for potentially dangerous fakes".[7] Taken that counterfeit medicament may not serve its purpose at all, as they are fake, or if being sub-standardized they again fail to heal or even worsen the patient's medical condition with its content that may trigger a variety of conditions, and having in mind that interest for the above-mentioned original medicament was very wide, the scope of negative consequences of use of its counterfeit version may be very worrying.

This case is far from isolated; rather, it reflects a broader, concerning trend. According to a 2013 study conducted by the United Nations Office on Drugs and Crime (UNODC), between one-third and two-thirds of the medicinal samples tested in East Asia and the Pacific were found to be fraudulent. This significant proportion highlights the widespread nature of counterfeit drug issues in the region, underscoring the urgent need for enhanced regulatory measures and increased vigilance in pharmaceutical markets.[8] According to the latest Pharmaceutical Security Institute research, the greatest number of counterfeit medicaments was in "North America (2442), followed by the Asia Pacific (1747), Latin America (770), the Near East (705), Eurasia (646), Europe (374) and Africa (187)…, and worldwide the number of incidents has been

---

https://www.reuters.com/business/healthcare-pharmaceuticals/rise-reports-fake-weight-loss-drugs-linked-shortage-real-thing-who-says-2024-01-29/

5 Wingrove

6 European Medicine Agency, "Ozempic", retrieved from https://www.ema.europa.eu/en/medicines/human/EPAR/ozempic.

7 Hart, Robert. "Fake Wegovy: Pharma Giant Novo Nordisk Reportedly Steps Up Efforts Tackling Illegal Weight Loss Drugs Sold Online", *Forbes,* December 18, 2023. Online at https://www.forbes.com/sites/roberthart/2023/12/18/fake-wegovy-pharma-giant-novo-nordisk-reportedly-steps-up-efforts-tackling-illegal-weight-loss-drugs-sold-online/?sh=bad10402966e

8 WHO.*WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products.* (World Health Organization, Geneva, 2017). www.who.int/medicines/regulation/ssffc/publications/GSMSreport_EN.pdf?ua=1

growing since 2015, and reaching its peak in 2021 with 5987 cases".[9] World Health Organization estimates that 10 percent of the medical products in low and middle-income countries are sub-standardized or falsified, while the highest share is in sub-Saharan African nations, where that rate is between 19-50 percent.[10] The data shows that the most often counterfeit are antibiotics (35%), followed by sexual impuissance treatment, painkillers, anti-malarial medicines, diabetes treatment, and heart treatment, allergy, and cancer treatments.[11] "Between 12% and 82% of anti-malarial drugs tested in Africa fail chemical analysis".[12] The fact that "the value of the global trade in counterfeit pharmaceuticals was up to USD 4.4 billion in 2016",[13] illustrates the prevalence of the problem. And its seriousness may be described through the consequences counterfeit medicaments cause like "severe health risks including death (due to the presence of toxins, lack of active ingredient), drug-resistant strains (microbial resistance, superbugs) and revenue loss (financial loss to private industry and government revenues)".[14] Therefore, trafficking in counterfeit medicines is a major global challenge that threatens the public health and safety of people around the world.

This research aims to delve deeper into the reasons behind counterfeiting, and its spread mainly in the developing world, especially in countries affected by war and turmoil, also where there are "weaknesses"[15] in legal regime and legislation that facilitate this phenomenon. It also highlights the importance of access to the right medicines, even if they are generic, at affordable prices.

---

[9] Fleck, Anna. "Counterfeit Drugs on the Rise Globally", *Statista,* May 24, 2023. Retrieved from https://www.statista.com/chart/30067/worldwide-counterfeit-pharmaceuticals-incidents/

[10] Fleck.

[11] *See* Bate, Roger. *Phake: the deadly world of falsified and substandard medicines.* Rowman & Littlefield, 2012; Ziniel, Francisca Anita Dommetieru. *Socio-Economic Impact of Counterfeitmedicine/Fake Drugs on Ghana Under SDG 3.* Diss. University of Ghana, 2021.

[12] United Nations Office on Drugs and Crime (UNODC). *Transnational Organized Crime in East Asia and the Pacific: A Threat Assessment.* (UNODC, 2013).

[13] Hallam, Christopher, and David R. Bewley-Taylor. "Mapping the world drug problem: Science and politics in the United Nations drug control system." *International Journal of Drug Policy* 21, no. 1 (2010): 1-3.

[14] UNODC. *Transnational Organized Crime in East Asia and the Pacific: A Threat Assessment,* p. 129.

[15] Ofori-Parku, Sylvester Senyo. "Fighting the global counterfeit medicines challenge: A consumer-facing communication strategy in the US is an imperative." *Journal of Global Health* 12 (2022): 03018.

The paper is structured into four distinct sections. The first section provides an overview of the factors contributing to the prevalence of counterfeit medicines, with a specific focus on their widespread occurrence in developing countries. In the second section, the discussion shifts to potential solutions, examining the role of international organizations, national regulatory bodies, and the importance of legislative reforms in addressing the issue. The third section presents a detailed case study of Indonesia, highlighting the country's efforts to combat counterfeit drugs through effective legislative measures and practical interventions. Finally, the paper concludes by summarizing key findings and offering recommendations for further action in the global fight against counterfeit medicines.

This paper argues that medicine counterfeiting thrives due to large financial gains and relatively low risk of detection compared to other criminal activities. Criminal networks involved in counterfeit medicines often exploit weak regulations, laws, and weak enforcement methods in developing countries, where oversight mechanisms and enforcement capacities may be limited by various factors, including political instability, conflict, and corruption. Developing countries, especially those facing wars and humanitarian crises, provide fertile ground for imitators to operate in secret, taking advantage of chaos and weak governance. Other factors also contribute to the spread of this transitory crime in some countries. This may include lack of resources, limited institutional capacity, corruption, and inadequate legal frameworks. In addition, counterfeiters often exploit porous borders, making it difficult for national authorities to effectively monitor and control the flow of counterfeit medicines.

Also, the high cost of original medicines can create a significant barrier to accessing essential medicines that relate to human life, especially for low-income individuals wherever they are and poor countries in particular. The lack of affordable medicines can drive vulnerable populations to look for cheaper alternatives, leaving them vulnerable to buying counterfeit medicines, thus worsening the problem.

The TRIPS of the WTO Agreement grants pharmaceutical companies exclusive patent protection for a specified period, though it is sometimes long. This protection prevents other manufacturers from producing generic versions of patented medicines, which limits competition and keeps medication prices high. This paper argues that by shortening the term of patent protection, poor countries can produce generic medicines, making them more accessible and affordable to their people and thus reducing the phenomenon of trafficking in counterfeit medicines.

The role of the WTO is also to ensure that bilateral and multiple trade agreements and policies do not impede access to affordable medicines. However, some developed countries, such as the United States, go to a more protective approach to their patents than the TRIPS agreement, which is known as TRIPS-Plus. Through initiatives such as the Doha Declaration on the TRIPS Agreement and Public Health, the WTO strives to strike a balance between protecting intellectual property rights and protecting public health interests, especially in developing countries.[16]

The WHO plays a crucial role in combating the smuggling of counterfeit medicines. It works closely with member states to strengthen regulatory systems, strengthen surveillance and monitoring, and enhance public awareness of the risks associated with counterfeit medicines. WHO also facilitates information exchange and cooperation between countries to address cross-border challenges. However, these efforts need to be intensified, especially in developing countries.

The global organization Interpol also plays a crucial role in combating cross-border smuggling of counterfeit medicines. They facilitate international cooperation and exchange of information between law enforcement agencies, support joint operations, and help dismantle criminal networks involved in the illegal trade in counterfeit medicines, but the phenomenon is still increasing.

Many pharmaceutical companies hold patents for essential medicines, which restricts generic production in poor countries. In addition, the complexities of drug manufacturing processes, lack of infrastructure, and limited technical expertise are significant barriers for these countries to start producing their own generic drugs.

Thus, it was found that all countries should update their criminal legislation to include severe penalties for those involved in trafficking in counterfeit medicines. Through enacting strict laws and imposing harsh penalties, the regime can act as a deterrent to potential counterfeiters and protect its citizens from the health risks associated with counterfeit medicines.

This paper concludes that trafficking in counterfeit medicines is a major threat to global health, with vulnerable populations in developing countries being the most affected. To combat this crime effectively, a multi-pronged approach is required, which includes international cooperation with international organizations such as the WTO, WHO and the Interpol,

---

[16] World Trade Organization. *Declaration on the TRIPS agreement and public health.* DOHA WTO MINISTERIAL 2001: TRIPS https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

strengthening legal systems, and consolidation national and international enforcement efforts. Thus, by prioritizing public health and promoting access to affordable medicines, the international community can collectively address this critical issue affecting the well-being of people around the world.

The following examines the causes of medicine counterfeiting and its remarkable prevalence in developing countries.

Etiology of Counterfeiting and Its Prevalence in Developing Countries

This paper suggests that the counterfeiting of medicines and their spread in developing countries can be attributed to a complex interplay of various factors, each exacerbating the other. These reasons include (i) economic, (ii) regulatory, (iii) social challenges, (iv) the influence of organized crime, and (v) the lack of healthcare access for vulnerable populations.

A. Economic Factors

One of the main drivers of medicine counterfeiting in developing countries is the lucrative economic opportunities it provides to criminal networks. Even in developed countries, as a report by the European Union Intellectual Property Office (EUIPO) and Europol shows, counterfeiting still pose a serious threat to the health and safety of consumers, as well as to the European economy.[17] Counterfeit medicines can be produced at a fraction of the cost of genuine medications, allowing criminals to reap substantial profits without facing the rigorous quality and safety standards associated with legitimate pharmaceutical manufacturing. The allure of these financial gains incentivizes these criminal enterprises to produce and distribute counterfeit medicines, often with little regard for the potential harm they cause to patients.[18]

Counterfeit pharmaceuticals constitute a highly profitable illegal market. Furthermore, this sector poses significant threats to public health, brand

[17] Europol, "Imports of counterfeit and pirated goods amounted to 119 billion euros in 2019". *Counterfeit and pirated goods get boost from pandemic, New Report confirms.* (Europol, March 2022). https://www.europol.europa.eu/media-press/newsroom/news/counterfeit-and-pirated-goods-get-boost-pandemic-new-report-confirms.

[18] Europol. *Counterfeit and pirated goods get boost from pandemic, New Report confirms.* Europol. https://www.europol.europa.eu/media-press/newsroom/news/counterfeit-and-pirated-goods-get-boost-pandemic-new-report-confirms>.

reputation, and pharmaceutical manufacturers' profits. Although traditionally prevalent in less developed markets, counterfeiters are now using digital platforms to infiltrate developed countries with robust distribution networks. Despite substantial investments in countermeasures, current tactics only effectively block around half of fake drugs.[19]

B. Challenging Regulations

Inadequate regulatory systems and weak law enforcement mechanisms in many developing countries also contribute significantly to the proliferation of counterfeit medicines.[20] Limited resources, corruption, and bureaucratic inefficiencies hinder the ability of regulatory agencies to effectively monitor and combat the illegal medicine trade. This creates an environment where counterfeiters can operate with relative impunity, evading detection and punishment for their illegal activities.[21] The weakness of national and international regulations, laws, and legislation is a central factor contributing to the exacerbation of the trade in counterfeit medicines. Counterfeiters exploit gaps and loopholes in regulatory frameworks to produce, distribute, and sell fake medications without facing significant consequences. Several aspects of the regulatory environment contribute to this dilemma.[22]

At the national level, inadequate pharmaceutical regulations and law enforcement enable counterfeiters to operate with relative ease. Some countries may lack comprehensive laws specifically targeting counterfeit medicines, leaving enforcement agencies with limited tools to combat the problem effectively.[23] Additionally, corruption and weak governance in certain regions

---

[19] Peter Behner, Marie-Lyn Hecht, and Fabian Wahl. *Fighting Counterfeit Pharmaceuticals: New Defenses for an Underestimated—and Growing—Menace*. (Strategy& PwC, 2017). https://www.strategyand.pwc.com/gx/en/insights/2017/fighting-counterfeit-pharmaceuticals/fighting-counterfeit-pharmaceuticals.pdf

[20] Glass, Beverley D. "Counterfeit drugs and medical devices in developing countries." *Research and Reports in tropical Medicine* (2014): 11-22.

[21] Ziavrou, Kalliroi S., Stephen Noguera, and Vassiliki A. Boumba. "Trends in counterfeit drugs and pharmaceuticals before and during COVID-19 pandemic." *Forensic Science International* 338 (2022): 111382.

[22] Dégardin, Klara, Yves Roggo, and Pierre Margot. "Forensic intelligence for medicine anti-counterfeiting." *Forensic science international* 248 (2015): 15-32.

[23] Guin, Ujjwal, Domenic Forte, and Mohammad Tehranipoor. "Anti-counterfeit techniques: From design to resign." *2013 14th International workshop on microprocessor test and verification*. IEEE, 2013; Hall, Christo. "Technology for combating counterfeit medicine." *Pathogens and Global Health* 106, no. 2 (2012): 73-76.

may hinder the enforcement of existing laws, allowing counterfeiters to evade detection and continue their illegal activities.

Internationally, the transnational nature of the counterfeit medicine trade poses significant challenges. Counterfeiters can take advantage of differing regulatory standards between countries to manufacture and distribute their products in regions with weaker enforcement. This international variation in regulations can make it difficult for law enforcement agencies to coordinate efforts and apprehend those involved in the trade.[24]

C. Social Factors

The social factors prevalent in developing countries play a role in the spread of counterfeit medicines. Lack of awareness among the general population about the risks associated with counterfeit medicines and the difficulty in distinguishing them from genuine products lead to an increased demand for cheaper alternatives. Patients seeking affordable healthcare solutions may unknowingly purchase counterfeit medications from unauthorized sources, further fueling the demand and perpetuating the cycle of counterfeiting.[25]

The global nature of the pharmaceutical supply chain and the increasing use of online marketplaces also facilitate the spread of counterfeit medicines in developing countries.[26] With complex supply networks spanning multiple countries, it becomes challenging to trace and intercept illegal products. Online platforms provide a convenient platform for counterfeiters to reach a broad audience while remaining anonymous and difficult to track. According to a 2019 report by the Organization for Economic Co-operation and Development (OECD) and the European Union Intellectual Property Office (EUIPO), international trade in counterfeit and pirated products could reach 3.3% of global trade.[27] In the EU, 5.8% of all imports from foreign countries are

---

[24] Astrazeneca, "Responsible Research", *Sustainability Update,* 2015. https://www.astrazeneca.com/content/dam/az/our-company/Sustainability/Responsible-Research.pdf

[25] Ziavrou, Noguera, and Boumba. "Trends in counterfeit drugs and pharmaceuticals before and during COVID-19 pandemic."

[26] Glass, "Counterfeit drugs and medical devices in developing countries."

[27] This total does not include counterfeits and pirated products produced and consumed domestically and the vast amount of pirated digital products distributed over the Internet. *See* Pérez-y-Soto, Danny Grajales. "Counterfeiting and piracy in 2021 – the global impact", *World Trademark Review*, May 11, 2021. https://www.worldtrademarkreview.com/global-guide/anti-counterfeiting-and-online-brand-enforcement/2021/article/counterfeiting-and-piracy-in-2021-the-global-impact.

estimated to be counterfeit and pirated goods, worth up to EUR 119 billion (USD 134 billion) in 2021.[28]

The challenges faced by the poor, particularly in developing countries, in obtaining medicines at reasonable prices are multifaceted and deeply rooted in socioeconomic disparities. Access to affordable and quality medicines is critical for the well-being and health of vulnerable populations, but several factors hinder their ability to access these essential medications.

One of the main reasons exacerbating the trade in counterfeit medicines is the high cost of genuine pharmaceutical products.[29] Pharmaceutical companies invest substantial resources in research, development, and obtaining regulatory approvals for new medicines, which often leads to higher prices to recoup these investments. As a result, many life-saving medications become unaffordable for the poor, leaving them with limited options and driving them towards seeking cheaper alternatives, which unfortunately may include counterfeit medicines.

The international trade and supply chain complexities also play a role in the high cost of medicines in developing countries. Import duties, taxes, and trade barriers can increase the prices of imported medicines, making them less accessible to the poor. Additionally, the influence of pharmaceutical companies and intellectual property rights can create barriers to the production of affordable generic drugs, further limiting the availability of cost-effective alternatives.[30]

To address these challenges and combat the trade in counterfeit medicines, a multi-pronged approach involving countries, the international community, and international organizations is essential: Overcoming the obstacles facing the manufacturing of generic medicines in poor societies is essential to address the challenges in obtaining affordable medicines for their populations.[31] Generic medicines are cost-effective alternatives to brand-name drugs and play a critical role in increasing access to essential medications. However, several barriers hinder the production and distribution of generic drugs in developing societies.

---

[28] Directorate-General for Trade and Economic Security Brussels. *Commission publishes latest Counterfeit and Piracy Watch List.* (European Commission, December 1, 2022). https://policy.trade.ec.europa.eu/news/commission-publishes-latest-counterfeit-and-piracy-watch-list-2022-12-01_en.

[29] Ziavrou, Noguera, and Boumba. "Trends in counterfeit drugs and pharmaceuticals before and during COVID-19 pandemic."

[30] World Health Organization. *WHO Guideline on Country Pharmaceutical Pricing Policies.* (Geneva: WHO, 2015).

[31] Yenet, Aderaw, Getinet Nibret, and Bantayehu Addis Tegegne. "Challenges to the availability and affordability of essential medicines in African countries: a scoping review." *ClinicoEconomics and Outcomes Research* 15 (2023): 443-458.

One significant obstacle is the stringent intellectual property protection and patent laws, as mandated by the TRIPS Agreement.[32] These laws grant pharmaceutical companies exclusive rights to produce and sell patented drugs for a specific period, limiting competition and hindering the entry of generic versions into the market. Developing societies often lack the capacity and resources to challenge patents or negotiate licensing agreements with patent holders, further restricting their ability to manufacture affordable generic medicines.[33]

To overcome these challenges, developing countries can benefit from the Doha Declaration on the TRIPS Agreement and Public Health, adopted by the WTO in 2001. The Doha Declaration reaffirmed the flexibilities available to member countries under TRIPS to protect public health interests. One crucial aspect of the Doha Declaration is the recognition of the right of governments to use compulsory licensing to access affordable medicines.

Under Article 31 of the TRIPS Agreement, (Other Use without Authorization of the Right Holder)[34] countries are permitted to issue compulsory licenses, which allow the government to authorize third parties to produce and sell generic versions of patented drugs without the consent of the patent holder. This provision is particularly vital for developing countries that face public health crises and need to access affordable medicines quickly.

The Doha Declaration clarified that the TRIPS Agreement should not prevent member countries from taking necessary measures to protect public health. It reaffirmed that the Agreement should be interpreted and

---

[32] The TRIPS Agreement imposes strict intellectual property protection and patent laws. This can be a significant obstacle because it may limit access to essential technologies and medicines, hindering innovation and making it challenging for countries to address public health needs. The stringent enforcement of intellectual property rights can lead to higher costs, reduced competition, and barriers to the transfer of technology, particularly in areas like healthcare where affordability and accessibility are crucial. *See* Wojahn, Patrick L. "A conflict of rights: intellectual property under TRIPS, the right to health, and AIDS drugs." *UCLA Journal of International Law and Foreign Affairs* 6, no. 2 (2001): 463-497.

[33] World Trade Organization. *Obligations and Exceptions: Under TRIPS, what are member governments' obligations on pharmaceutical patents?*. Available online at https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm.

[34] World Trade Organization. *Uruguay round Agreement TRIPS: Part II — Standards concerning the availability, scope and use of Intellectual Property Rights*. Available online at https://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm.

implemented in a manner supportive of member countries' right to protect public health and promote access to medicines for all.[35]

However, under the intellectual property clause of the Jordan-US Free Trade Agreement, Jordan is obligated to follow the non-WTO-recommended TRIPS-plus rules imposed by the United States, which puts a developing country like Jordan at a disadvantage. Compliance with these strict rules has resulted in higher prices for medicines imported from the United States.[36] The complex patent provisions in the agreement (the TRIPS-plus rules) have led to higher drug costs in Jordan. The agreement obligates Jordan to longer protection periods for US medication patents, preventing the production of affordable generic drugs.[37]

As a result, inflated medicine prices have burdened Jordan's healthcare system, increasing healthcare costs for both the government and citizens.[38] This situation poses challenges in providing accessible and affordable medical services to all segments of the population. Moreover, restrictions on the production of generic medicines have left Jordanians with limited alternatives to basic treatments, increasing the likelihood that some will turn to fake medicines because of their cheap prices.[39]

Unfortunately, despite the importance of public health, Jordan has not received the benefits outlined in the Doha Declaration on the TRIPS Agreement and public health. Whereas, the fourth paragraph of the Doha Declaration affirms that the TRIPS Agreement must be interpreted and implemented in a way that supports the rights of WTO members to protect

---

[35] Abbott, Ryan Benjamin. "Access to Medicines and Intellectual Property in Jordan." *Intellectual Property Watch,* July 23 (2012). Available at SSRN: https://ssrn.com/abstract=2116096

[36] The US should not coerce developing countries into adopting TRIPS-plus IP protections through bilateral and regional trade agreements through other forms of pressure and inducement. At about 20 countries that accepted such an agreement with US. *See* Office of the United States Trade Representative, "Free Trade Agreements", available online at https://ustr.gov/trade-agreements/free-trade-agreements.

[37] Lopert, Ruth, and Deborah Gleeson. "The high price of "free" trade: US trade agreements and access to medicines." *Journal of Law, Medicine & Ethics* 41, no. 1 (2013): 199-223.

[38] Malpani, Rohit. "All Costs, No Benefits: How TRIPS plus intellectual property rules in the US-Jordan FTA affect access to medicines", *Oxfam Briefing Paper*, no. 102 (2007)

[39] Abbott, Frederick M. "The Doha Declaration on the TRIPS Agreement and Public Health and the contradictory trend in bilateral and regional free trade agreements." *Quaker United Nations Office (Geneva)(QUNO), Occasional Paper* 14 (2004).

public health and encourages access to medicines for different groups of citizens.[40]

Given the current situation, it is necessary to address the impact of TRIPS-plus rules on access to medicines and to explore ways to mitigate these effects. Engaging in discussions with relevant international organizations, such as the WTO and the WHO, could help advocate for the United States to abandon the TRIPS-plus rules not recommended by the WTO.[41]

D. The Influence of Organized Crime in Counterfeit Medicine

Transnational organized crime involves illegal activities carried out by coordinated groups or networks across multiple countries, often seeking financial gain through violence, corruption, or related actions. Modern advancements like globalization and technology, including cryptocurrencies, have transformed how such crime operates. These activities can undermine global public health by producing and trafficking counterfeit medicines on a large scale. This issue is particularly prominent in low- and middle-income nations, where the WHO estimates that up to one in ten medical products are substandard or fake. Counterfeit drug trade often spans borders, with manufacturing in one country and distribution to many, even infiltrating legitimate global drug supply chains. This can result in devastating consequences, causing over a million deaths annually due to substandard or adulterated medicines, with Africa being significantly impacted.[42]

Organized crime plays a central role in exacerbating the problem of trafficking in counterfeit medicines, especially in developing countries. Organized crime groups benefit from the counterfeit drug market because of their high profit margins and relatively low risk of being sued.

In developing countries, the counterfeit drug trade thrives due to various factors, including weak regulatory systems and limited drug control resources that make these countries vulnerable to the infiltration of counterfeit drugs into

---

[40] World Trade Organization. *Declaration on the TRIPS agreement and public health.* DOHA WTO MINISTERIAL 2001: TRIPS.

[41] TRIPS-Plus rule is not only inconsistent with the WTO/TRIPS protection requirement. Nevertheless, it is also depriving the citizens their fundamental human rights to life and health recognized in international law. Furthermore, it is a clear violation of the Doha Public Health Declaration Paragraph IV that emphasized the TRIPS Agreement should not prevent Members from taking measures to protect public health.

[42] Caparini, Marina. "Transnational organized crime: A threat to global public goods." *Stockholm International Peace Research Institute, SIPRI* (2022). https://www.sipri.org/commentary/topical-backgrounder/2022/transnational-organized-crime-threat-global-public-goods.

their markets.[43] Organized crime networks exploit these vulnerabilities, directing their illicit products to countries with less stringent controls and oversight.

One example of how organized crime is exacerbating is the rampant trade in counterfeit anti- malarial in sub-Saharan Africa, where demand for affordable medicines is high.[44] Criminal groups exploit this demand by flooding the market with fake anti-malarial drugs that do not contain the active ingredients needed to fight the disease. As a result, patients do not receive the treatment they need, leading to prolonged illness, drug resistance, and even death.

The involvement of organized crime networks in the trafficking of counterfeit medicines also undermines public confidence in the healthcare system.[45] Patients may inadvertently purchase counterfeit medicines from seemingly legitimate sources, such as local pharmacies or online retailers. This erodes confidence in the quality and efficacy of the original medicines, making it more difficult for health care authorities to treat diseases effectively.

Moreover, profits from counterfeit drug trafficking often go back to criminal networks, financing other illegal activities such as human trafficking, arms smuggling, and drug trafficking. Hence, the continuation of the criminal cycle that further impedes development and stability in vulnerable societies.

To combat this problem, a multi-pronged approach is necessary. Developing countries must strengthen their health legislation and systems, invest in combating organized crime and strengthen law enforcement capacities. International cooperation and intelligence sharing are also important in disrupting the networks responsible for trafficking in counterfeit medicines. In addition, public awareness campaigns by international organizations can help educate consumers about the risks of purchasing medicines from unverified sources.

E. The Lack of Healthcare Access for Vulnerable Populations

Another challenge is the lack of comprehensive healthcare coverage and social safety nets in developing countries.[46] This paper argues that the inability

---

[43] Trade, Illicit. *Trade in counterfeit pharmaceutical products*. OECD Publishing Paris, 2020.

[44] United Nations. "Fake medicines kill almost 500,000 sub-Saharan Africans a year: UNODC report", *UN News,* 2023. Retrieved from https://news.un.org/en/story/2023/02/1133062

[45] Buckley, Gillian J., and Lawrence O. Gostin. "The effects of falsified and substandard drugs." *Countering the Problem of Falsified and Substandard Drugs*. National Academies Press (US), 2013.

[46] Glass, "Counterfeit drugs and medical devices in developing countries."

of the poor to access adequate health care exacerbates the phenomenon of counterfeit medicine trade. When poor communities do not have access to reliable and affordable healthcare services, they may resort to buying medicines from informal sources, making them vulnerable to buying counterfeit medicines. Criminal networks exploit this weakness by flooding the market with counterfeit medicines that are cheaper than the original.

Many poor countries suffer from a heavy burden due to infectious diseases such as malaria and immunodeficiency, especially marginalized communities whose members may resort to buying antibiotics from unregistered pharmacies. These fake medicines often contain inactive ingredients, which leads to failure to treat diseases and thousands of deaths.[47]

The responsibility and duty to reduce the phenomenon of trafficking in counterfeit medicines extends to all parties of the international community, as cooperation is crucial in intercepting counterfeit medicines at the borders and tracking down the networks involved in their production and promotion. As emphasized in this paper, a comprehensive approach that combines law enforcement, public awareness campaigns, and regulatory coordination is necessary to effectively combat the counterfeit drug trade.[48]

The effects of counterfeit medicines extend beyond the borders of the poor country, which means the interdependence of the global drug supply chain. Counterfeit medicines can reach other countries through various channels, including cross-border trade and online platforms.[49] These counterfeit medicines pose risks to public health around the world, as they can contribute to the emergence of drug-resistant strains, undermine confidence in healthcare systems, and impose economic burdens on countries dealing with the consequences of counterfeit medicines.

Thus, improving access to a good quality healthcare in vulnerable communities plays a pivotal role in limitation the proliferation of counterfeit medicines. In both rural and urban settings, government hospitals often serve as the primary healthcare providers. However, developing countries face challenges in providing adequate healthcare services, potentially enabling the spread of counterfeit medicines. To address this, it's imperative to implement

---

[47] Musgrove, Philip, Riadh Zeramdini, and Guy Carrin. "Basic patterns in national health expenditure." *Bulletin of the World Health Organization* 80 (2002): 134-146.

[48] Ahmadiani, Saeed, and Shekoufeh Nikfar. "Challenges of access to medicine and the responsibility of pharmaceutical companies: a legal perspective." *DARU Journal of Pharmaceutical Sciences* 24, no. 1 (2016): 13.

[49] Strobl, S. "Counterfeit drugs in industrialized and developing countries–A comparison." *Faculty of Mathematics and Natural Sciences, University of Bonn, Germany* (2011): 1-64.

healthcare system reforms that cater to individual needs. The WHO outlines the characteristics of vulnerable communities and essential healthcare services that hospitals must sustain. Among the recommended strategies is the establishment of formal healthcare structures and the allocation of national budgets supported by international aid in developing nations.[50] Through undertaking these measures, the broader effect is enhanced healthcare accessibility and quality, which is vital in combatting the circulation of counterfeit medications.

The following discusses the possible solutions proposed by this paper to combat counterfeit medicines and to address the exacerbation of the counterfeit medicine trade, both at the national and international levels.

Possible Solutions to Combatting Counterfeit Medicines

A. Strengthening the Pharmaceutical Regulations

Developing countries should invest in strengthening their pharmaceutical regulations to ensure they are comprehensive, up-to-date, and aligned with international standards. Adequate legislation should be enacted to specifically address counterfeit medicines, imposing severe penalties on offenders. Governments also need to invest in the training and capacity building of law enforcement agencies to detect, investigate, and prosecute cases related to counterfeit medicines effectively. Strengthening cooperation between law enforcement agencies and regulatory authorities can enhance intelligence-sharing and cross-border collaboration.

This paper emphasizes the importance for developing nations to address the proliferation of counterfeit medicines and align with global norms by harmonizing their pharmaceutical regulations. This entails adopting established guidelines from influential bodies like the WHO and the International Council on Harmonization (ICH).[51] By unifying regulations encompassing medicine

---

[50] Toro, Nuria. "Who global strategy on integrated people-centred health services (IPCHS)/Estrategia mundial en servicios de salud integrada centrado en las personas (IPCHS)." *International Journal of Integrated Care* 15 (2015).

[51] International Council on Harmonization (ICH), https://www.ich.org/. *See also* Niazi, Sarfaraz K., Waleed Mohammed Al-Shaqha, and Zafar Mirza. "Proposal of international council for harmonization (ICH) guideline for the approval of biosimilars." *Journal of Market Access & Health Policy* 11, no. 1 (2023): 2147286; Ojha, Abhijeet, and Samir Bhargava. "International council for harmonisation (ICH) guidelines." *Regulatory affairs in the pharmaceutical industry*. Academic Press, 2022, pp. 47-74.

registration, manufacturing practices, branding, and quality control, these countries can establish a more cohesive regulatory framework, bolstering their ability to accurately identify and combat counterfeit medicines.

Furthermore, it necessitates an integrated approach that encompasses activities such as personnel training, fortifying the infrastructure for medication testing and quality assessment, and enhancing surveillance systems to swiftly detect counterfeits. Equipping regulatory bodies with these capabilities empowers them to effectively oversee the pharmaceutical landscape and promptly identify falsified medications.

Additionally, becoming part of international agreements equips these nations with a legal framework to prosecute the production and distribution of counterfeit medical products. Harnessing advanced technological applications can also provide an avenue for consumers to verify the legitimacy and origin of pharmaceutical products.

Simultaneously, developing countries should fortify their enforcement mechanisms and elevate public awareness through regular inspections, audits, and vigilant market surveillance. This proactive stance ensures the swift identification and removal of counterfeit products from circulation.

B. Enhanced Collaboration between Countries

Enhanced collaboration between countries is essential to tackle the transnational nature of the counterfeit medicine trade. International agreements and conventions can facilitate information exchange, harmonize regulations, and streamline efforts to combat counterfeit medicines. Raising awareness among the general population, healthcare professionals, and regulatory authorities about the dangers of counterfeit medicines is also crucial. Educating people on how to identify legitimate sources and products can help reduce the demand for fake drugs.

Utilizing advanced technologies, such as track-and-trace systems, holograms, and blockchain, can help authenticate genuine medicines throughout the supply chain and prevent counterfeit products from entering the market. One of the very good examples of the collaboration of countries in the fight against this type of crime and EUROPOL is in the action "Shield" that took place back in 2022. Namely, Italy, Spain, Greece and France led this action and were accompanied by 28 other countries, including Bosnia and Herzegovina. The police broke 59 criminal organizations and arrested nearly

350 individuals who were participating in dealing and transporting fake medicaments.[52] In total 10, 5 million medicament units were confiscated.

C. Cooperation with Pharmaceutical Companies

Facts show insufficient interest on the part of pharmaceutical companies in the field of health needs. According to the World Health Organization, more than 1 billion people are affected by tropical diseases, which lead to a significant reduction in life expectancy and quality of life. Given the higher rate of these diseases in low-income countries, it can be said that this situation can cause significant discrimination between high- and low-income communities, not only in terms of health, but also in economic terms as a result of the lower level of health.[53]

This attitude by the pharmaceutical industry, causes a decrease or imbalance in access to medicines, and thus inequalities in health between and within societies, which can be seen as a violation of human rights. Since, health is considered as a basic human right, as it is stated in article 12 of International Covenant on Economic, Social and Cultural Rights.[54] According to the United Nations, the responsibilities enshrined in the Universal Declaration of Human Rights are not only an obligation of member states, but the private sector also has human rights responsibilities.[55]

Therefore, cooperation between pharmaceutical companies will be vital for poor societies in the fight against counterfeit medicines. Collaborative efforts could focus on monitoring supply chains, reporting suspicious activity, and removing counterfeit products from circulation.

Initially, governments can negotiate with pharmaceutical companies to secure lower medicine prices for essential treatments. This can be achieved through bulk purchasing agreements, price controls, and pooled procurement mechanisms to ensure medicines are more affordable and accessible to the

---

[52] Anonymous. "Učestvovala i BiH: Velika akcija Europola, krivotvorili i krijumčarili lijekove [BiH also participated: Major Europol operation, counterfeit and smuggled medicines]", *N1 Info*, December 19, 2022 https://n1info.ba/vijesti/ucestvovala-i-bih-velika-akcija-europola-krivotvorili-i-krijumcarili-lijekove/

[53] World Health Organization. *Global Health Observatory (GHO) data: Neglected Tropical Diseases.* (Geneva: WHO, 2019).

[54] UN General Assembly, *International Covenant on Economic, Social and Cultural Right*, 1966. https://digitallibrary.un.org/record/57676

[55] Ahmadiani, and Nikfar. "Challenges of access to medicine and the responsibility of pharmaceutical companies: a legal perspective."

people.[56] Also, developing countries should prioritize investments in healthcare infrastructure, including the establishment of well-equipped and well-staffed healthcare facilities and pharmacies in rural and underserved areas. This can improve access to genuine medicines and reduce the demand for counterfeit drugs.

Moreover, encouraging the production and use of generic medicines can significantly lower drug costs. International organizations can support countries in implementing policies that facilitate the production and distribution of safe and affordable generic medicines. Furthermore, countries need to strengthen their regulatory systems and law enforcement efforts to combat the trade in counterfeit medicines. Collaborative efforts between nations and international organizations can support capacity building and information sharing to identify and apprehend counterfeiters.

Raising awareness among the general public, healthcare providers and pharmacists about the risks associated with counterfeit medicines is also critical. Information campaigns can help people identify legitimate sources and products, reducing demand for counterfeit medicines. Encouraging local production of essential medicines can reduce reliance on costly imports and create jobs within the pharmaceutical industry. International organizations can provide technical assistance and support to help countries build their drug manufacturing capacities.

Lastly, international organizations, such as the WHO and the WTO, can play a vital role in promoting international cooperation to address the global challenges of drug affordability and counterfeit drug trade. They can enhance harmonization of regulations, reset intellectual property rights and monitor trade policies to ensure better access to real, affordable medicines.[57]

We suggest that countries consider tax exemptions for essential medicines and active pharmaceutical ingredients. It is suggested also that countries consider any tax cuts or breaks, while taking measures to ensure the policy leads to lower drug prices for patients in developing countries. By implementing these solutions collectively, countries, the international community, and international organizations can make significant progress in improving access to affordable medicines for the poor and reducing the demand for counterfeit medications. These efforts are essential for protecting the health and well-being

---

[56] PLoS Medicine Editors. "Drug companies should be held more accountable for their human rights responsibilities." *PLoS medicine* 7, no. 9 (2010): e1000344.

[57] Lee, Joo-Young, and Paul Hunt. "Human Rights Responsibilities of Pharmaceutical Companies in Relation to Access to Medicines." *Journal of Law, Medicine & Ethics* 40, no. 2 (2012): 220-233.

of vulnerable populations and promoting equitable access to healthcare worldwide. The following examines issue of patent protection, the TRIPS agreement, and how TRIPS-Plus limits poor people's access to medicines in developing countries that have committed themselves to free trade agreements with developed countries.

D. The role of the WTO Patent Protection and the TRIPS Agreement

Patent protection and TRIPS agreement play a significant role in shaping the challenges faced in obtaining affordable medicines, particularly in developing countries.[58] While patent protection is crucial for incentivizing innovation and investment in pharmaceutical research, it can also create barriers to access by granting exclusive rights to the pharmaceutical companies, allowing them to charge high prices for their products.[59] TRIPS, as an international agreement under the WTO, sets minimum standards for intellectual property protection, including patents, which can impact access to medicines, especially in developing nations.[60]

Under TRIPS, member countries are required to grant patents for inventions, including pharmaceutical products, for a minimum period of 20 years.[61] This means that pharmaceutical companies can hold exclusive rights to produce and sell certain medications, which limits competition and can keep drug prices artificially high. Consequently, the extended period of patent protection can hinder the production of affordable generic versions of essential medicines, preventing access for many vulnerable populations in developing countries.[62]

The TRIPS agreement has faced criticism for its potential negative impact on public health and access to medicines. Some argue that the stringent patent protection measures disproportionately favor pharmaceutical companies,

---

[58] Khwaileh, Khaled. "Jordan's international trading regime and integration with the Arab region through trade liberalization". *Thesis.* Macquarie University, 2022. https://doi.org/10.25949/19443308.v1.

[59] Gurgula, Olga. "Strategic patenting by pharmaceutical companies–should competition law intervene?." *IIC-International Review of Intellectual Property and Competition Law* 51, no. 9 (2020): 1062-1085.

[60] Khwaileh, Khaled. *The US-Jordan free trade agreement: benign or malign for the economic development of Jordan?.* Diss. Macquarie University.

[61] Ćuzović, Sreten, Svetlana Sokolov Mladenović, and Đorđe Ćuzović. "Trade in counterfeit products in conditions of crisis caused by the COVID-19 pandemic." *Counterfeiting and Fraud in Supply Chains.* Emerald Publishing Limited, 2022, pp. 121-145.

[62] Jurua, Maria. "Access to drugs at risk: securing access to medicines for least developed countries." *Africa Development* 42, no. 1 (2017): 101-120.

making it difficult for developing countries to access affordable medicines. This situation can lead to a paradox where life-saving drugs are unaffordable for those who need them the most, potentially driving patients to seek cheaper but riskier alternatives, such as counterfeit medicines.[63]

To address the exacerbation of the trade in counterfeit medicines and improve access to affordable medications, the WTO and the TRIPS agreement can consider implementing various solutions. The TRIPS agreement already allows for certain flexibilities that balance intellectual property protection with public health needs. Developing countries can utilize compulsory licensing, granting licenses to produce generic versions of patented drugs without the consent of the patent holder.[64] Therefore, by promoting awareness and encouraging countries to make use of these flexibilities, the WTO can ensure access to affordable medicines, especially in regions with limited resources. This approach can help mitigate the negative impact of counterfeit medicines by fostering a competitive market for generic drugs and driving down prices of essential medications.

Another effective measure the WTO can explore is the possibility of reducing patent protection periods for essential medicines that address public health challenges in developing countries.[65] Through shortening patent terms, the timely entry of generic versions can be facilitated, promoting competition in the pharmaceutical market and making essential medicines more affordable. This approach aligns with the TRIPS agreement's objectives of striking a balance between intellectual property rights and public health priorities. Shorter patent protection periods for crucial medications can have a significant impact on healthcare access in developing countries, ensuring that life-saving treatments reach those in need without unnecessary financial burdens.

The WTO can also play a critical role in supporting technology transfer initiatives that establish manufacturing capacity for essential medicines within developing countries.[66] This approach enables local production of medications,

---

[63] Subhan, Junaid. "Scrutinized: the TRIPS agreement and public health." *McGill Journal of Medicine: MJM* 9, no. 2 (2006): 152.

[64] Wong, Hilary. "The case for compulsory licensing during COVID-19." *Journal of global Health* 10, no.1 (2020): 010358.

[65] Tenni, Brigitte, et al. "What is the impact of intellectual property rules on access to medicines? A systematic review." *Globalization and health* 18, no. 1 (2022): 40.

[66] The WTO can support technology transfer initiatives by facilitating agreements that allow developing countries to build manufacturing capacity for essential medicines. This involves negotiating terms that enable the transfer of technology and knowledge from developed to developing nations, promoting local production of critical medicines. This can enhance access to affordable healthcare solutions and addressing public health needs.

leading to lower costs and enhanced accessibility for local populations. By promoting technology transfer, the WTO can help bridge the gap between developed and developing countries in terms of pharmaceutical production capabilities. This not only increases the availability of affordable medicines but also strengthens the self-reliance and sustainability of healthcare systems in these regions.[67]

Considering the challenges faced by Least Developed Countries (LDCs), the WTO can explore the option of extending or making permanent exemptions for LDCs from TRIPS requirements. This extension would grant LDCs more time to implement stricter patent rules, providing a temporary reprieve for their healthcare systems. Such exemptions can contribute to better access to essential medicines and healthcare services in these vulnerable regions. Additionally, the WTO can actively promote and support initiatives like the Medicines Patent Pool (MPP) that facilitate voluntary licensing agreements between pharmaceutical companies and generic manufacturers. Collaborative initiatives such as MPP can increase the availability of affordable medicines in developing countries and contribute to global efforts in combating counterfeit drugs.

To further enhance accessibility, the WTO can work towards reducing trade barriers and tariffs on pharmaceutical products, making them more affordable and accessible globally. Lowering import duties can significantly impact medicine costs in developing countries, enabling these regions to procure essential medicines at more reasonable prices.[68] Additionally, the establishment of a robust monitoring and reporting system for counterfeit drug incidents, in collaboration with member countries, can help identify trends and areas of concern. This information can lead to targeted interventions and better-equipped efforts to combat the proliferation of counterfeit medicines.

In conclusion, through the implementation of these multifaceted strategies, the WTO and the TRIPS agreement can contribute significantly to mitigating the challenges in obtaining affordable medicines, curbing the demand for counterfeit medications, and promoting equitable access to healthcare for all, especially in developing countries. Balancing intellectual property protection with public health needs is a critical step towards ensuring

---

See WIPO, "Committee on Development and Intellectual Property (CDIP)", 2012. http://193.5.93.81/edocs/mdocs/mdocs/en/cdip_9/cdip_9_inf_5.pdf

[67] World Trade Organization. *Promoting access to medical technologies and innovation Intersections between public health, intellectual property and trade*. WTO, 2013.

[68] Helble, Matthias, and Benjamin Shepherd. *Trade in health products: Reducing trade barriers for better health*. No. 643. ADBI Working Paper, 2017.

the availability of essential medicines at affordable prices for those who need them the most. Thus, to coordinate with the WTO and the TRIPS Agreement, developing countries can make use of the flexibilities provided by the Doha Declaration paragraph 4. They can issue compulsory licenses for essential medicines that are unaffordable or unavailable due to patent barriers. By doing so, they can enable domestic pharmaceutical companies to produce generic versions, reducing drug prices and ensuring access to medicines for their populations.

Furthermore, developing countries can engage in capacity building and technical assistance initiatives with the support of international organizations and the WTO. These efforts can help strengthen their regulatory and intellectual property systems, enhance manufacturing capabilities, and improve expertise in negotiating licensing agreements.

International collaboration is vital in supporting developing countries' efforts to produce generic medicines. The WTO can provide guidance and support in utilizing the TRIPS Agreement's flexibilities effectively.[69] It can also encourage technology transfer and promote partnerships between countries to foster the production of affordable medicines. Additionally, the WTO can facilitate knowledge sharing and best practices among member countries to strengthen their legal frameworks, streamline patent examination processes, and bolster their capacity to implement public health-driven policies. By taking advantage of the Doha Declaration and coordinating with the World Trade Organization and the TRIPS Agreement, developing countries can promote an environment conducive to the manufacture of generic drugs. This approach will also help in overcoming obstacles to obtaining affordable medicines, thus avoiding the purchase of counterfeit medicines.

E. Role of the World Health Organization (WHO)

The WHO assumes a vital role in combatting the trade in counterfeit medicines and addressing the challenges faced, particularly in developing countries.[70] To bolster its efforts and strengthen support for these nations, the WHO can implement a range of strategies. Enhanced surveillance and monitoring systems must be established, whereby the WHO collaborates with member countries to create robust mechanisms for tracking and reporting incidents of counterfeit medicines. This entails gathering data on counterfeit

---

[69] Lopert, Ruth, and Deborah Gleeson. "The high price of "free" trade: US trade agreements and access to medicines." *Journal of Law, Medicine & Ethics* 41, no. 1 (2013): 199-223.

[70] WHO. *Substandard and Falsified Medical Products.*

drug incidents, sharing information, and identifying trends and hotspots, enabling targeted interventions to combat the proliferation of fake drugs effectively. Joint research initiatives with developing countries can also be pursued to gain deeper insights into the unique challenges they face, fostering evidence-based approaches to address the issue comprehensively.

Capacity building and technical assistance programs play a pivotal role in enabling developing countries to combat counterfeit medicines effectively. The WHO can provide targeted support to these nations, conducting training programs for regulatory authorities, law enforcement agencies, and healthcare professionals. Via imparting knowledge on identifying and tackling counterfeit drugs, these capacity-building efforts empower local institutions with the expertise and resources necessary to address the problem at its source. Moreover, the WHO should actively urge pharmaceutical companies to invest in developing countries to bolster local manufacturing capabilities. By fostering partnerships and technology transfers, pharmaceutical companies can contribute to enhancing access to affordable and legitimate medications, consequently reducing the demand for counterfeit products in these regions.

To intensify its efforts and remain at the forefront of combating counterfeit medicines, the WHO should seek increased funding and support from member countries and donor organizations. Adequate resources are essential to implement comprehensive and sustained anti-counterfeit medicine programs, allowing the WHO to make a tangible difference in protecting public health worldwide. Through joint research projects with developing countries, the WHO can better understand the challenges they face and design tailored interventions that address their specific needs. So, by fostering stronger collaborations with pharmaceutical companies, the organization can encourage investments in developing countries, enhancing local manufacturing capacity and ensuring access to safe and affordable medications.

While the efforts of the WHO in training a global network of over 550 regulatory staff in 141 Member States to report substandard and falsified medical products to the WHO Global Surveillance and Monitoring System are commendable, it is essential to acknowledge that the scale of the challenge is vast and constantly evolving. The magnitude of the issue of substandard and falsified medical products requires continuous and collaborative efforts from various stakeholders.[71]

The establishment and enforcement of robust regulatory standards for pharmaceutical products represent critical steps in the fight against counterfeit

[71] WHO. *Substandard and Falsified Medical Products.*

medicines. The WHO can work closely with member countries to formulate and enforce stringent quality and safety standards for medicines, promoting good manufacturing practices and reducing the prevalence of substandard and counterfeit drugs. Through advocacy for policy and legal reforms at both national and international levels, the WHO can encourage countries to implement stronger penalties for counterfeiters and enhance border controls.[72] Additionally, global partnerships and collaborative initiatives should be facilitated, involving organizations like Interpol, the World Customs Organization (WCO), and pharmaceutical industry associations. This ensures improved information exchange, intelligence-sharing, and coordinated actions against counterfeit drug networks on an international scale.

In brief, the WHO plays a central role in the fight against counterfeit medicines, especially in developing countries where the need for affordable and safe medications is most acute. By implementing strategies such as enhanced surveillance, capacity building, public awareness, and coordination with international partners, the WHO can lead the charge in curbing the trade in counterfeit medicines. Joint research initiatives with developing countries provide a holistic understanding of the issue, enabling evidence-based solutions, while urging pharmaceutical companies to invest in these regions fosters local manufacturing capabilities and reduces the demand for counterfeit products. To combat the evolving nature of counterfeit medicine trade, the WHO must continually adapt its strategies and collaborate with countries and international organizations to protect public health effectively. With increased funding and support, the WHO can implement comprehensive and sustained anti-counterfeit medicine programs, ensuring access to safe, effective, and affordable medicines for all.

F. Role of Interpol in Combating Counterfeit Medicine Smuggling

This research does not deny Interpol's efforts to combat the global trade in counterfeit medicines. Interpol, through its Illicit Goods and Global Health (IGGH) programme, cooperates with Member States, law enforcement agencies and international organizations in the field of pharmaceutical crime. The IGGH program participates in various initiatives and operations aimed at dismantling criminal networks involved in the production, distribution and sale of counterfeit medical products.[73]

---

[72] WHO. *Guidelines for the development of measures to combat counterfeit drugs*. Geneva: WHO, 1999.

[73] *See* Zabyelina, Yuliya, and Stephen Noguera. "Organized Crime and the Pharmaceutical Industry." *The Private Sector and Organized Crime*. Routledge, 2022, pp. 224-241.

Region-specific initiatives, such as Operation Afya in South Africa and Operation Heera targeting West Africa, also focus on tackling criminal groups involved in the manufacture and distribution of counterfeit medicines. Interpol also has initiatives such as Operation Vigilant Interdiction (OVI) which has been set up in response to crimes related to COVID-19. Furthermore, Interpol cooperates with regional organizations, such as AFRIPOL, in operations such as "*Operation Flash*" that specifically target counterfeit and illicit vaccines, medicines and medical devices across Africa.[74]

Additionally, the UNODC's knowledge and experience in combating transnational organized crime can play a pivotal role in targeting the criminal elements responsible for the production and distribution of counterfeit medicines. So, by focusing on disrupting illicit supply chains and apprehending offenders, the UNODC can significantly impede the flow of counterfeit drugs and bring perpetrators to justice. Interpol, as the world's largest international police organization, possesses unique capabilities in facilitating global law enforcement cooperation. Its secure communication channels and databases can serve as a central repository for information sharing between member countries. By coordinating joint operations and providing technical assistance to developing countries with weak law enforcement, Interpol can enhance their capabilities in detecting and intercepting counterfeit medicines.

Forming this global partnership would enable the involved organizations to streamline their efforts and eliminate duplication of work. It would create a centralized mechanism for intelligence sharing, analysis, and coordination, enabling a more effective response to the evolving tactics of counterfeit medicine traffickers. Furthermore, this collaborative approach would foster synergies among the organizations, leading to more targeted and impactful interventions in combating counterfeit medicines.

To address the current failure of the international community in confronting the threat of counterfeit medicines, this proposed mechanism must garner support and commitment from member countries and relevant stakeholders. Adequate funding and resources will be essential to sustain the partnership's activities and initiatives. Also, through mobilizing the collective strengths of the WHO, UNODC, and Interpol, this global partnership can

---

[74] Layachi, Ouarda Belkacem. "International and National Obligations to Protect from the Risks of Pharmaceutical Crime: The Crime of Counterfeit Pharmaceutical Products in the COVID-19 Crisis." *Systematic Reviews in Pharmacy* 11, no. 2 (2020).

make significant strides in the fight against counterfeit medicines and protect public health on a global scale.[75]

To put it briefly, the establishment of a mechanism overseen by the WHO, UNODC, and Interpol offers a promising avenue to confront the scourge of counterfeit medicines worldwide. As a result of focusing on patient safety, cross-border crime prevention, and law enforcement field operations, this global partnership can effectively combat the trade in counterfeit medicines and disrupt criminal networks involved in their production and distribution. Through collaboration and coordination, the international community can make meaningful progress in safeguarding public health and ensuring access to safe and genuine medications for all.

G. Modernizing Criminal Legislation and Strengthening Penalties

Modernizing national criminal legislation and introducing international criminal legislation are indeed necessary measures to effectively confront the crime of trafficking in counterfeit medicines. As the trade in counterfeit medicines becomes more sophisticated and globalized, legal frameworks must adapt to address the evolving challenges and ensure that perpetrators are appropriately penalized. One of the latest significant regional motions was bringing the Convention of the Council of Europe on Counterfeiting Pharmaceuticals (also known as MEDICRIM), in 2022. It has been ratified by 18 countries. Its aim, as described in Article 1, is to incriminate some criminal offences, protect victims of those offences and to improve national and international collaboration. In its second part, it recommends incrimination of these criminal offences: manufacturing of counterfeit medical products; supplying, offering to supply and trafficking in counterfeit medical products; the falsification of documents; the unauthorized manufacturing or supplying of medicinal products and the placing on the market of medical devices which do not comply with conformity requirements and production and similar criminal offenses which include threats to public health. And just as an illustration, Republic of Croatia is one of the countries from its region that in line with the Convention has prescribed criminal offence Counterfeiting of Medicines or Medical Products (article 185 of the Criminal Code). It is prescribed in two basic and in three aggravated forms. The first basic form criminalizes counterfeit or modification of medicine, its active substance, auxiliary active substance, medicinal product, components and accessories. The sanction prescribed is six

[75] Mackey, Tim K., and Bryan A. Liang. "Improving global health governance to combat counterfeit medicines: a proposal for a UNODC-WHO-Interpol trilateral mechanism." *BMC Medicine* 11, no. 1 (2013): 233.

months to five years of imprisonment. The second basic form, prescribed with the same sanction may consist of one of these alternative actions: acquirement, offer to acquire, store, import or export, or put into circulation as genuine, counterfeit or modifies medicine, its active substance, auxiliary active substance, medicinal product, components and accessories[76]. The aggravated forms, which are punishable with imprisonment of up to three years, refer to situations related to modification of its package and indication card. The hardest form of this criminal offence would exist if the perpetrator commits any of the previous forms with the use of trust as an expert, producer or dealer, or makes it available through the mass distribution of information systems, such is internet. The sanction for this form is imprisonment of between 1-8 years[77]. Together with imprisonment, the cumulative sanction for all these forms is a measure of the security of the products and mechanisms. Precisely observed, this legal solution prescribes quite strict sanctions and with the width of its prescription style consumes a variety of different actions that may fall under its scope, including the use of Internet for the distribution of such medicines. Therefore, it is quite in line with the social needs and state in practice.

A neighboring country, Bosnia and Herzegovina, mirrors the other side of the coin. It has ratified the Convention but still did not incriminate those suggested criminal offences. The strategy related to this issue has been brought in 2022, which includes the creation of a variety of committees, and expert councils that would propose legal modifications and further developments in this matter[78]. Until then, more general criminal offences cover indirectly matters of counterfeit of medicines, such is Illicit Trade – observing its trade[79].

---

[76] Article 185 (2) Criminal Code of Republic of Croatia.

[77] Article 185 (6) of the Criminal Code of Republic of Croatia.

[78] Bosnia and Herzegovina. *Izvještaj o radu Multisektorske radne grupe za praćenje implementacije Konvencije Vijeća Evrope o krivotvorenju medicinskih proizvoda i sličnim krivičnim djelima koja predstavljaju prijetnju javnom zdravlju za 2022* [Report on the work of the Multisectoral Working Group for Monitoring the Implementation of the Council of Europe Convention against the Counterfeiting of Medicinal Products and Similar Criminal Offences Representing a Threat to Public Health for 2022]. https://mcp.gov.ba/publication/read/javne-konsultacije-o-dokumentu-izvjestaj-o-radu-multisektorske-radne-grupe-za-pracenje-implementaci?pageId=97

[79] Due to the specific constitutional organization, there are four criminal codes applicable in this country. *See more* Kazić-Çakar, Ena. "A Brief Discourse about Corruption in Bosnia and Herzegovina". In *Bosnia and Herzegovina and European Integration: Obstacles and Challenges*, ed. by Dženita Šiljak and Kristian L. Nielsen (pp. 78–93). International University of Sarajevo. *See also* Article 212 of the Criminal Code of Bosnia and Herzegovina, Article 267 of the Criminal Code of Federation of Bosnia and Herzegovina, Article 261 of the Criminal Code of Brčko District of Bosnia and Herzegovina.

However, all criminal codes applicable in Bosnia and Herzegovina are not fully harmonized - the act of this criminal offence nor the sanction, which brings legal uncertainty among the people of that state. In addition to that, the Criminal Code of Republika Srpska prescribes a criminal offence of Production and Placing on the Market of Products Harmful for Treatment (art. 202), and threats with cumulative sanctions of imprisonment up to two years and a monetary fine for "manufacture, sale or placement on the market drugs or other means of treatment that are harmful to health". Although this act is not nominally and content-wise fully correspond to the criminal offences prescribed by the MEDICRIM, it indirectly covers cases of counterfeit medicines, as they may be harmful to health. So this would be an illustration that some countries are not only struggling with a correct legislative motion to deal with the counterfeit medicines but also with specific internal obstacles such is the lack of harmonization. Its future legislative process should not only include incrimination of that criminal offence, but also criminalization of it in a harmonized manner in all the codes[80].

At the national level, modernizing criminal legislation involves updating existing laws or enacting new ones to specifically address the crime of smuggling counterfeit medicines. For the countries that ratified this convention is to incriminate the above-mentioned criminal offences. This includes defining clear and comprehensive legal definitions of counterfeit medicines, establishing the elements of the offense, and delineating the scope of criminal liability for individuals and entities involved in the production, distribution, or sale of counterfeit medicines.[81]

Modernized legislation should also provide authorities with adequate powers to investigate and prosecute counterfeit medicine cases effectively. This may include granting law enforcement agencies the authority to conduct surveillance, gather evidence, and collaborate with other agencies to dismantle counterfeit medicine networks. Additionally, mechanisms for international cooperation and information exchange should be integrated into national laws to facilitate coordination with other countries in tackling transnational counterfeit medicine operations. The MEDICRIM prescribes procedural provisions related to the investigation of these cases and collaboration.

Introducing international criminal legislation can further strengthen the global response to the crime of trafficking in counterfeit medicines. Collaborative efforts at the international level can harmonize legal frameworks,

---

[81] Attaran, Amir. "Stopping murder by medicine: introducing the model law on medicine crime." *The American journal of tropical medicine and hygiene* 92, no. Suppl 6 (2015): 127.

facilitate extradition of suspects, and improve coordination between countries in investigating and prosecuting cross-border cases. An international legal framework would also help ensure that counterfeit medicine smugglers cannot easily evade justice by moving operations across national borders.

Tightening penalties for the crime of smuggling counterfeit medicines is a crucial aspect of deterrence and enforcement. Significantly increasing sanctions, fines, and custodial sentences for offenders sends a strong message that the international community takes this crime seriously. Stricter penalties act as a deterrent to potential counterfeiters and discourage their involvement in illicit activities. Moreover, ensuring that penalties are proportionate to the severity of the offense and its potential consequences is essential. Counterfeit medicines can have serious health implications and even lead to loss of life. Therefore, penalties should be commensurate with the harm caused, considering factors such as the scale of the operation, the risks posed to public health, and the criminal intent behind the act. However, one should not forget that together with heavy punishment, the efficiency of the judicial system plays essential role in the formula and is what may bring us to reaching the prevention of crime.

Via reforming national criminal legislation, introducing international criminal legislation, and tightening penalties, countries can create a comprehensive and robust legal framework to combat the trade in counterfeit medicines. These measures enhance the ability of law enforcement agencies to detect, investigate, and prosecute counterfeit medicine cases effectively, thereby disrupting criminal networks and protecting public health. Moreover, such legal reforms create an environment where counterfeit medicine traffickers face significant consequences for their actions, reducing the appeal of engaging in this illicit trade. Additionally, international cooperation through shared legal frameworks fosters collaboration between countries, enabling a united front against the global menace of counterfeit medicines.

Nevertheless, it is crucial to strike a balance in enforcement, ensuring that penalties do not inadvertently affect individuals with legitimate intentions, such as parallel importers or those dealing with minor infractions unknowingly. To achieve an effective and fair response, collaboration with international organizations, such as Interpol, the WHO, and the WTO, is vital. Through working together, countries can harmonize legal standards, share best practices, and coordinate efforts in a concerted global endeavor to combat the trafficking of counterfeit medicines.

H. Raising the Awareness of the Problem Through Education

It is doubtless that improvement in joint efforts in fight against this type of crime will give positive results. The same will general and special prevention through the punishment system. However, prevention from critical and health-threatening events may be achieved with two-fold education. The lower, ground level of education would be related with the pharmacists, who work directly in the distribution of medicines. Forensic education in which they are taught how to recognize fake packages, signs, medicaments, and gray area suppliers would be an important step. The second type of education and raising of awareness would be directed to the consumers. Education, public debates, public lectures on what counterfeit medicines are, what are their risks, and consequences, from where not to purchase medicines, how to report suspicious products and dealers, would be beneficial and give effects.[82]

A Brief Case Study of State Oof Affairs Regarding Illegal Trade in Counterfeit Medicines in Indonesia

According to the Global Organized Crime Index[83], Indonesia has a 6,85 crime score, and regarding the global crime parameters, regarding the crime, it holds "20th place out of 193 countries, 8th place in Asia, and 2nd in SE Asian Countries"[84]. Geopolitically and geo-strategically it holds very important position, it is fourth largest population in the developing countries, it is near China, thus it is suitable transit point, including transit of fake goods. Therefore, it is important to examine the way how this country deals with the counterfeit drugs, what is its legal strategy and framework, and it position in INTERPOL when it comes to the collaboration among countries in fighting this crime.

The challenge of fighting against the Counterfeit Medicines according to the statistics is present in Indonesia, as it is in many other countries of the world.

---

[82] Potent example is the Alliance for Safe Online Pharmacies (ASOP Global) and the National Association of Boards of Pharmacy (NABP) "which began the development of an awareness campaign focused on educating US consumers regarding the dangers of counterfeit medicine and the risks of purchasing counterfeit medicine from unknown, online sources". *See more* Steketee, Tara. "Educating Consumers on the Danger of Counterfeit", *Bad Meds* 8, no. 4 (2023). https://bpp.msu.edu/magazine/educating-consumers-bad-meds-december2023/.

[83] Global Organized Crime Index, *Indonesia.* https://ocindex.net/country/indonesia

[84] *Ibid.*

According to Prakoso et al.[85] in 2016 counterfeit drugs in "Indonesia reached 2 billion of total amount pharmaceutical business", although the preventive and repressive measures to fight it exist in this country. The data from 2011, "given by the International Pharmaceutical Manufacturers Group presents that 11% of medicines marketed in Indonesia are counterfeit products"[86]. According to the same source, the data given by the Indonesian National Agency for Drug and Food Control, in the period 2013-2015, the most counterfeit medicines are "for erectile dysfunction, antibiotics, antipyretics-analgetic, antihypertensive and antimalarial medicines"[87], while the most counterfeit brands are Blopress, Cialis, Viagra, Ponstan, etc[88].

The high prices of medicines are common to the entire world, and a numerous population of Indonesia are important predictors for existence of this crime, as many people turn to buying products that are less expensive, particularly through online market which helps them to purchase anonymously. Prakoso et al. estimate that the prices of medicaments in Indonesia are higher than in the neighboring countries[89], and at the same time they emphasize the fact of growing organized crime groups that enable counterfeiting medicines and their approach on the market. At the same time, as this phenomenon grows, the lack of effectiveness of experts to distinguish original products from fake ones, on one hand, and lack of reports by the consumers to report this kind of goods due to the "consumer-unfriendly legal provisions"[90], on other hand, are enabling the trade in counterfeit medicines to be more extensive.

---

[85] Prakoso, Bismo Teguh, Adrianus E. Meliala, and Arthur Josias Simon Runturambi. "The Politico-Criminal Configuration Relationship between Organized Crime and the State as a Form of State-Organized Crime in the Phenomenon of Production and Circulation of Counterfeit Drugs in Indonesia." *International Journal of Social Science and Human Research* 4, no. 4 (2021): 678-684.

[86] Marlyna, H., and A. Sardjono. "Research report on the knowledge, experience, and attitude of consumers towards counterfeit medicine in Jakarta: A legal analysis." in Harkrisnowo, H., Hikmahanto J., and Yu Un O. (ed.) *Law and Justice in a Globalized World: Proceedings of the Asia-Pacific Research in Social Sciences and Humanities, Depok, Indonesia, November 7-9, 2016: Topics in Law and Justice.* 1st ed. London: Routledge, 2017, pp. 15-22

[87] Marlyna, and Sardjono.

[88] Marlyna, and Sardjono.

[89] Prakoso, Meliala, and Runturambi. "The Politico-Criminal Configuration Relationship between Organized Crime and the State as a Form of State-Organized Crime in the Phenomenon of Production and Circulation of Counterfeit Drugs in Indonesia."

[90] Marlyna, and Sardjono. "Research report on the knowledge, experience, and attitude of consumers towards counterfeit medicine in Jakarta: A legal analysis."

The approach of Indonesia in fighting this problem is set in several levels. Namely, it has a legislative framework which is a combination of criminal law and civil/commercial law approach, and quite efficient practical measures which are counted to be effective in disabling potential counterfeit, or at least trade with such goods.

a) Legal Framework

Indonesia has a set of laws that through the combination of criminal and civil law, and particularly consumer law directly or indirectly regulates counterfeiting medicines and its prevention. *The Criminal Crook Code of Indonesia, The Regulation No. 36 of 2009 concerning well-being, the Regulation 1999 concerning buyer assurance, the Declaration N.193/KAT/B.7/71, and the Regulation No. 1010/Markes/Pen/XI/2008 concerning Drug Registration* are just a few to mention.

For example, *Declaration No.193* defines that the medication as "a substance or a mix of materials planned to be utilized in laying out a finding, forestalling, eliminating, restoring sickness or side effects of disease, injuries or illness, physical and profound anomalies in people or creatures, and to enhance or decorate the body or portions of the human body". This provision sets what medicine is, in order to clearly interpret what counterfeit medicine may be. The *Regulation No. 1010* specifies what counterfeit drugs are, and finds them as "drugs that are produced by unauthorized parties based on applicable laws and regulations, producing of drugs with marking that imitate the identity of drug others who already have the dissemination permit"[91].

Next, the *Regulation No. 36/2009* prescribes two particularly important articles for this topic. The punitive disposition is regulated with article 196., and threatens with imprisonment of a limit of 10 years and a fine with a limit of 1 million of Rupiah, if an individual who deliberately supports, induces or disseminates drug arrangements or potentially clinical gadgets that don't fulfill

[91] Amanda, R., and Minarosa M. "Criminal Action Responsibility Against Drug Counterfeiters According Indonesian Criminal Code and Law Number 36 of 2009 Concerning Health." In *Proceedings of the 3rd International Conference on Law, Social Science, Economics, and Education, ICLSSEE 2023, 6 May 2023, Salatiga, Central Java, Indonesia.* Salatiga, Indonesia: EAI, 2023. *See also* Sari, Chatrin Intan. "Consumer protection on illegal drugs cases in Indonesia." *Indonesia Media Law Review* 1, no. 1 (2022): 63-80; Hapsari, Paundria Dwijo, Awallia Septiyana Putri, and Henzie Kerstan. "Legal Policy for Drug Users in Indonesia and the Netherlands." *Journal of Creativity Student* 7, no. 1 (2022): 35-66.

the guidelines[92]" whose standards for security and quality are set by the Law. It is visible that three potential actions are punishable, which are supporting, inducing or disseminating drug arrangements. The sanction should have preventive function, as it is set strict. Additionally, the article 197 sets another punitive disposition, and threatens with more strict sanction of maximum 15 years of imprisonment and fine of 1,5 billion of Rupiah, for "deliberately producing or disturbing pharmaceutical preparate or medical devices without distribution permission. Namely, the *Regulation of the Minister of Health No. 1010/Menkes/Pen/XI/2008 concerning Drug Regulation*, sets conditions on the trader and the goods, in order to be eligible to be disseminated. Those conditions are consumed in the Dissemination Permit, "which is endorsement for drug to be conveyed inside Indonesia and those medicaments should have following characteristics:

1) Convincing viability and sufficient security demonstrated through creative tests and clinical preliminaries;
2) Quality tests that mark the prerequisites as surveyed from the creation interaction as per great medication assembly practices;
3) The checking contains total and objective data that can consume the appropriate normal and safe utilization of medicaments;
4) As per requirement of society"[93].

According to Yuliani et al.[94] "the criminal provisions are regulated to prevent procurement, misuse or storage of pharmaceutical preparations and or medical devices that can endanger the community by Parties" and "they represent Threat to Economy, Public safety, and they suppress competitiveness in the business field[95]. The Criminal Code sets criminal liability to individuals, while the Regulation 36/2009 expands that liability to legal persons as well[96].

The Criminal Code through articles 386 and 204 regulates these criminal acts. According to paragraph one of article 386 of the Criminal Code of

---

92 Amanda, and Minarosa. "Criminal Action Responsibility Against Drug Counterfeiters According Indonesian Criminal Code and Law Number 36 of 2009 Concerning Health."

93 Amanda, and Minarosa.

94 Yuliani, Evelina, Widodo T. Novianto, and Hari Purwadi. "The Urgency of Law Enforcement of Illegal Medicine Distributions in Indonesia." *Journal of Health Policy and Management* 4, no. 2 (2019): 76-85.

95 Yuliani, Novianto, and Purwadi. *See also* Yunus, Nur Rohim, et al. "Drug Abuse as an Extra-Ordinary Crime: Some Legal and Political Debates." *Jurnal Scientia Indonesia* 8, no. 1 (2022): 71-88; Nuryaasiinta, Cut Mayang Widya. "How Far is Consumer Protection in the Health Care Sector?." *Unnes Law Journal* 6, no. 1 (2020): 47-72.

96 Amanda, and Minarosa. "Criminal Action Responsibility Against Drug Counterfeiters According Indonesian Criminal Code and Law Number 36 of 2009 Concerning Health."

Indonesia, it is threatened with imprisonment of maximum four years to "any individual for selling, offering or conveying food, drink or medication which he knows to be falsified and disguise it"[97]. The offence is a typical example of a two-act criminal offence. Not only are its acts selling, offering or conveying the incriminate goods, but person is aware of its nature and disguise it. This means that this can be only inventive criminal offence, and knowledge is an essential element of the body of the crime. The active subject can be any person. The next paragraph of the same article defines when food, drink and medication are falsified. According to this provision they're falsified in the event that their worth or value is decreased on the grounds that they have been blended in with something different. This provision helps the court to establish the falsification, avoiding the existence of legal standard or unequal legal qualification.

In article 204 (1), the heavy sanction of fifteen years of imprisonment is set for "any individual who sells, offers, conveys or disseminates products, which are known to imperil the life and the strength of individuals, despite the fact that the risky nature is notified"[98]. Active subject can be any person, while the incriminated acts are selling, offering, conveying or disseminating products. The essential element of body of crime are characteristics of the products, and those are that it imperils the life and the strength of individual. The aggravated form of this criminal offence is prescribed in the next paragraph, where the aggravating circumstance is passing of a person, due to the above described act. In that case, the sanction is sentence to life detainment or detainment for a specific time of 20 years.

b) Collaboration of Indonesia on International level in fight against counterfeit medicines

Apart from this, practically Indonesia is involved in international cooperation if fighting counterfeiting medicines. It is a member state included in INTERPOL's Global Illicit Medicines Operation[99]. The operation named PANGEAXVI "which ran from 3-10 October, has led to 72 arrests worldwide, the seizure of potentially dangerous pharmaceuticals worth more than USD 7 million, 325 new investigations and the closure of more than 1,300 criminal websites"[100].

---

[97] Article 386 (1) Criminal Code of Indonesia.

[98] Article 204 of Criminal Code of Indonesia.

[99] *See* Mackey, Tim K., and Bryan A. Liang. "Improving global health governance to combat counterfeit medicines: a proposal for a UNODC-WHO-Interpol trilateral mechanism." *BMC Medicine* 11, no. 1 (2013): 233.

[100] Mackey, and Liang

A similar successful operation led by INTERPOL, and supported by the World Health Organization's (WHO) International Medical Products Anti-counterfeiting Task Force (IMPACT) was the Operation Storm II (July-November 2009). "It provided a platform for collaboration between national police, customs drug regulatory authorities from eight countries (Cambodia, China, Indonesia, Laos, Myanmar, Singapore, Thailand and Vietnam[101]", and it resulted with more than 30 arrests and more than 100 pharmacies being closed.

When it comes to the most recent developments, in December 2024 ASEANPOL joined INTERPOL in conducting Operation PANGEA XVII. "The briefing emphasized the importance of a coordinated, multi-sectoral approach to addressing the growing threat of counterfeit pharmaceutical crimes"[102]. This iteration marks a significant evolution, incorporating not only law enforcement but also prosecutors, private sector actors, and shipping companies in tackling the issue. "Participants were trained in methods to detect counterfeit pharmaceuticals, trace their origins, and preserve evidence, utilizing supply chain analysis, forensic tools, and international databases"[103]. The session underscored the severe impact of counterfeit drugs on public health and safety, with offenders now prioritized for international arrest and extradition through INTERPOL's Red Notices. The ASEANAPOL Secretariat's involvement highlights the global commitment to combating transnational pharmaceutical crime and enhancing public health security across ASEAN nations and globally.

Conclusion

In conclusion, the trade in counterfeit medicines represents a significant and growing threat to global public health, with both developing and developed nations vulnerable to its devastating consequences. This illicit trade thrives due to a confluence of factors, including inadequate legal frameworks, widespread corruption, economic instability, and ongoing conflicts. These elements create an environment conducive to criminal activities, where the proliferation of counterfeit drugs undermines public health and violates both national and international laws. The severe nature of this crime necessitates urgent and comprehensive legislative action to address its multifaceted impact.

---

[101] INTERPOL applauds Southeast Asia Operation Storm II's success in disrupting trade of counterfeit medical products, www.interpol.int

[102] www.aseanpol.org

[103] *Ibid.*

Addressing the trade in counterfeit medicines requires a coordinated approach that includes the harmonization of legal frameworks and the strengthening of national and international legislation. To combat the illicit trade effectively, there is a need for updated laws and harsher penalties for those involved in smuggling networks. Furthermore, tackling the root causes of poverty and unemployment in developing countries is critical in reducing the vulnerability of citizens to counterfeit drug dealers. Supporting the ability of these countries to produce affordable, genuine medicines through collaboration with international organizations, such as the WHO and the WTO, can help strike a balance between intellectual property protection and public health.

International collaboration is essential to tackling the complex challenge of counterfeit medicines. While organizations like the WHO, WTO, and Interpol have made important strides in curbing this issue, further cooperation with the United Nations is needed to enhance global efforts. This collaboration could involve simplifying mechanisms for the production of generic medicines and intensifying efforts against smuggling operations. The case study of Indonesia, which has made substantial progress in legislative and collaborative measures to combat counterfeit drugs, provides a promising example for other nations. By embracing a global partnership, leveraging the strengths of international organizations, and strengthening enforcement, the world can protect public health and ensure that access to safe, authentic medicines becomes a fundamental right for all.

References

Abbott, Frederick M. "The Doha Declaration on the TRIPS Agreement and Public Health and the contradictory trend in bilateral and regional free trade agreements." *Quaker United Nations Office (Geneva)(QUNO), Occasional Paper* 14 (2004).

Abbott, Ryan Benjamin. "Access to Medicines and Intellectual Property in Jordan." *Intellectual Property Watch,* July 23 (2012). Available at SSRN: https://ssrn.com/abstract=2116096

Ahmadiani, Saeed, and Shekoufeh Nikfar. "Challenges of access to medicine and the responsibility of pharmaceutical companies: a legal perspective." *DARU Journal of Pharmaceutical Sciences* 24, no. 1 (2016): 13.

Amanda, R., and Minarosa M. "Criminal Action Responsibility Against Drug Counterfeiters According Indonesian Criminal Code and Law Number 36 of 2009 Concerning Health." In *Proceedings of the 3rd International*

Conference on Law, Social Science, Economics, and Education, ICLSSEE 2023, 6 May 2023, Salatiga, Central Java, Indonesia. Salatiga, Indonesia: EAI, 2023.

Anonymous. "Učestvovala i BiH: Velika akcija Europola, krivotvorili i krijumčarili lijekove [BiH also participated: Major Europol operation, counterfeit and smuggled medicines]", *N1 Info*, December 19, 2022 https://n1info.ba/vijesti/ucestvovala-i-bih-velika-akcija-europola-krivotvorili-i-krijumcarili-lijekove/

Astrazeneca, "Responsible Research", *Sustainability Update,* 2015. https://www.astrazeneca.com/content/dam/az/our-company/Sustainability/Responsible-Research.pdf

Attaran, Amir. "Stopping murder by medicine: introducing the model law on medicine crime." *The American journal of tropical medicine and hygiene* 92, no. Suppl 6 (2015): 127.

Bate, Roger. *Phake: the deadly world of falsified and substandard medicines.* Rowman & Littlefield, 2012; Ziniel, Francisca Anita Dommetieru. *Socio-Economic Impact of Counterfeitmedicine/Fake Drugs on Ghana Under SDG 3*. Diss. University of Ghana, 2021.

Bosnia and Herzegovina. *Criminal Code of Bosnia and Herzegovina.*

Bosnia and Herzegovina. *Izvještaj o radu Multisektorske radne grupe za praćenje implementacije Konvencije Vijeća Evrope o krivotvorenju medicinskih proizvoda i sličnim krivičnim djelima koja predstavljaju prijetnju javnom zdravlju za 2022* [Report on the work of the Multisectoral Working Group for Monitoring the Implementation of the Council of Europe Convention against the Counterfeiting of Medicinal Products and Similar Criminal Offences Representing a Threat to Public Health for 2022]. https://mcp.gov.ba/publication/read/javne-konsultacije-o-dokumentu-izvjestaj-o-radu-multisektorske-radne-grupe-za-pracenje-implementaci?pageId=97

Buckley, Gillian J., and Lawrence O. Gostin. "The effects of falsified and substandard drugs." *Countering the Problem of Falsified and Substandard Drugs*. National Academies Press (US), 2013.

Caparini, Marina. "Transnational organized crime: A threat to global public goods." *Stockholm International Peace Research Institute, SIPRI* (2022). https://www.sipri.org/commentary/topical-backgrounder/2022/transnational-organized-crime-threat-global-public-goods.

Ćuzović, Sreten, Svetlana Sokolov Mladenović, and Đorđe Ćuzović. "Trade in counterfeit products in conditions of crisis caused by the COVID-19

pandemic." *Counterfeiting and Fraud in Supply Chains.* Emerald Publishing Limited, 2022, pp. 121-145.

Dégardin, Klara, Yves Roggo, and Pierre Margot. "Forensic intelligence for medicine anti-counterfeiting." *Forensic Science International* 248 (2015): 15-32.

Directorate-General for Trade and Economic Security Brussels. *Commission publishes latest Counterfeit and Piracy Watch List.* (European Commission, December 1, 2022). https://policy.trade.ec.europa.eu/news/commission-publishes-latest-counterfeit-and-piracy-watch-list-2022-12-01_en.

European Medicine Agency, "Ozempic", retrieved from https://www.ema.europa.eu/en/medicines/human/EPAR/ozempic.

Europol, "Imports of counterfeit and pirated goods amounted to 119 billion euros in 2019". *Counterfeit and pirated goods get boost from pandemic, New Report confirms.* (Europol, March 2022). https://www.europol.europa.eu/media-press/newsroom/news/counterfeit-and-pirated-goods-get-boost-pandemic-new-report-confirms.

Europol. *Counterfeit and pirated goods get boost from pandemic, New Report confirms.* Europol. https://www.europol.europa.eu/media-press/newsroom/news/counterfeit-and-pirated-goods-get-boost-pandemic-new-report-confirms>.

Fleck, Anna. "Counterfeit Drugs on the Rise Globally", *Statista,* May 24, 2023. Retrieved from https://www.statista.com/chart/30067/worldwide-counterfeit-pharmaceuticals-incidents/

Glass, Beverley D. "Counterfeit drugs and medical devices in developing countries." *Research and Reports in tropical Medicine* (2014): 11-22.

Global Organized Crime Index, *Indonesia.* https://ocindex.net/country/indonesia

Guin, Ujjwal, Domenic Forte, and Mohammad Tehranipoor. "Anti-counterfeit techniques: From design to resign." *2013 14th International workshop on microprocessor test and verification.* IEEE, 2013; Hall, Christo. "Technology for combating counterfeit medicine." *Pathogens and Global Health* 106, no. 2 (2012): 73-76.

Gurgula, Olga. "Strategic patenting by pharmaceutical companies–should competition law intervene?." *IIC-International Review of Intellectual Property and Competition Law* 51, no. 9 (2020): 1062-1085.

Hallam, Christopher, and David R. Bewley-Taylor. "Mapping the world drug problem: Science and politics in the United Nations drug control system." *International Journal of Drug Policy* 21, no. 1 (2010): 1-3.

Hapsari, Paundria Dwijo, Awallia Septiyana Putri, and Henzie Kerstan. "Legal Policy for Drug Users in Indonesia and the Netherlands." *Journal of Creativity Student* 7, no. 1 (2022): 35-66.

Hart, Robert. "Fake Wegovy: Pharma Giant Novo Nordisk Reportedly Steps Up Efforts Tackling Illegal Weight Loss Drugs Sold Online", *Forbes,* December 18, 2023. Online at https://www.forbes.com/sites/roberthart/2023/12/18/fake-wegovy-pharma-giant-novo-nordisk-reportedly-steps-up-efforts-tackling-illegal-weight-loss-drugs-sold-online/?sh=bad10402966e

Helble, Matthias, and Benjamin Shepherd. *Trade in health products: Reducing trade barriers for better health.* No. 643. ADBI Working Paper, 2017.

International Council on Harmonization (ICH), https://www.ich.org/.

Jurua, Maria. "Access to drugs at risk: securing access to medicines for least developed countries." *Africa Development* 42, no. 1 (2017): 101-120.

Kazić-Çakar, Ena. "A Brief Discourse about Corruption in Bosnia and Herzegovina". In *Bosnia and Herzegovina and European Integration: Obstacles and Challenges*, ed. by Dženita Šiljak and Kristian L. Nielsen (pp. 78–93). International University of Sarajevo.

Khwaileh, Khaled. "Jordan's international trading regime and integration with the Arab region through trade liberalization". *Thesis.* Macquarie University, 2022. https://doi.org/10.25949/19443308.v1.

Khwaileh, Khaled. *The US-Jordan free trade agreement: benign or malign for the economic development of Jordan?*. Diss. Macquarie University.

Layachi, Ouarda Belkacem. "International and National Obligations to Protect from the Risks of Pharmaceutical Crime: The Crime of Counterfeit Pharmaceutical Products in the COVID-19 Crisis." *Systematic Reviews in Pharmacy* 11, no. 2 (2020).

Lee, Joo-Young, and Paul Hunt. "Human Rights Responsibilities of Pharmaceutical Companies in Relation to Access to Medicines." *Journal of Law, Medicine & Ethics* 40, no. 2 (2012): 220-233.

Lopert, Ruth, and Deborah Gleeson. "The high price of "free" trade: US trade agreements and access to medicines." *Journal of Law, Medicine & Ethics* 41, no. 1 (2013): 199-223.

Lopert, Ruth, and Deborah Gleeson. "The high price of "free" trade: US trade agreements and access to medicines." *Journal of Law, Medicine & Ethics* 41, no. 1 (2013): 199-223.

Mackey, Tim K., and Bryan A. Liang. "Improving global health governance to combat counterfeit medicines: a proposal for a UNODC-WHO-Interpol trilateral mechanism." *BMC Medicine* 11, no. 1 (2013): 233.

Mackey, Tim K., and Bryan A. Liang. "Improving global health governance to combat counterfeit medicines: a proposal for a UNODC-WHO-Interpol trilateral mechanism." *BMC Medicine* 11, no. 1 (2013): 233.

Malpani, Rohit. "All Costs, No Benefits: How TRIPS plus intellectual property rules in the US-Jordan FTA affect access to medicines", *Oxfam Briefing Paper*, no. 102 (2007)

Marlyna, H., and A. Sardjono. "Research report on the knowledge, experience, and attitude of consumers towards counterfeit medicine in Jakarta: A legal analysis." in Harkrisnowo, H., Hikmahanto J., and Yu Un O. (ed.) *Law and Justice in a Globalized World: Proceedings of the Asia-Pacific Research in Social Sciences and Humanities, Depok, Indonesia, November 7-9, 2016: Topics in Law and Justice.* 1st ed. London: Routledge, 2017, pp. 15-22

Musgrove, Philip, Riadh Zeramdini, and Guy Carrin. "Basic patterns in national health expenditure." *Bulletin of the World Health Organization* 80 (2002): 134-146.

Niazi, Sarfaraz K., Waleed Mohammed Al-Shaqha, and Zafar Mirza. "Proposal of international council for harmonization (ICH) guideline for the approval of biosimilars." *Journal of Market Access & Health Policy* 11, no. 1 (2023): 2147286.

Nuryaasiinta, Cut Mayang Widya. "How Far is Consumer Protection in the Health Care Sector?." *Unnes Law Journal* 6, no. 1 (2020): 47-72.

Office of the United States Trade Representative, "Free Trade Agreements", available online at https://ustr.gov/trade-agreements/free-trade-agreements.

Ofori-Parku, Sylvester Senyo. "Fighting the global counterfeit medicines challenge: A consumer-facing communication strategy in the US is an imperative." *Journal of Global Health* 12 (2022): 03018.

Ojha, Abhijeet, and Samir Bhargava. "International council for harmonisation (ICH) guidelines." *Regulatory affairs in the pharmaceutical industry.* Academic Press, 2022, pp. 47-74.

Pérez-y-Soto, Danny Grajales. "Counterfeiting and piracy in 2021 – the global impact", *World Trademark Review*, May 11, 2021. https://www.worldtrademarkreview.com/global-guide/anti-counterfeiting-and-online-brand-enforcement/2021/article/counterfeiting-and-piracy-in-2021-the-global-impact.

Peter Behner, Marie-Lyn Hecht, and Fabian Wahl. *Fighting Counterfeit Pharmaceuticals: New Defenses for an Underestimated—and Growing—Menace.* (Strategy& PwC, 2017).

https://www.strategyand.pwc.com/gx/en/insights/2017/fighting-counterfeit-pharmaceuticals/fighting-counterfeit-pharmaceuticals.pdf

PLoS Medicine Editors. "Drug companies should be held more accountable for their human rights responsibilities." *PLoS medicine* 7, no. 9 (2010): e1000344.

Prakoso, Bismo Teguh, Adrianus E. Meliala, and Arthur Josias Simon Runturambi. "The Politico-Criminal Configuration Relationship between Organized Crime and the State as a Form of State-Organized Crime in the Phenomenon of Production and Circulation of Counterfeit Drugs in Indonesia." *International Journal of Social Science and Human Research* 4, no. 4 (2021): 678-684.

Republic of Croatia. *Criminal Code of Republic of Croatia.*

Sari, Chatrin Intan. "Consumer protection on illegal drugs cases in Indonesia." *Indonesia Media Law Review* 1, no. 1 (2022): 63-80.

Steketee, Tara. "Educating Consumers on the Danger of Counterfeit", *Bad Meds* 8, no. 4 (2023). https://bpp.msu.edu/magazine/educating-consumers-bad-meds-december2023/.

Strobl, S. "Counterfeit drugs in industrialized and developing countries–A comparison." *Faculty of Mathematics and Natural Sciences, University of Bonn, Germany* (2011): 1-64.

Subhan, Junaid. "Scrutinized: the TRIPS agreement and public health." *McGill Journal of Medicine: MJM* 9, no. 2 (2006): 152.

Tenni, Brigitte, et al. "What is the impact of intellectual property rules on access to medicines? A systematic review." *Globalization and health* 18, no. 1 (2022): 40.

Toro, Nuria. "Who global strategy on integrated people-centred health services (IPCHS)/Estrategia mundial en servicios de salud integrada centrado en las personas (IPCHS)." *International Journal of Integrated Care* 15 (2015).

Trade, Illicit. *Trade in counterfeit pharmaceutical products.* OECD Publishing Paris, 2020.

UN General Assembly, *International Covenant on Economic, Social and Cultural Right*, 1966. https://digitallibrary.un.org/record/57676

United Nations Office on Drugs and Crime (UNODC). *Transnational Organized Crime in East Asia and the Pacific: A Threat Assessment.* (UNODC, 2013).

United Nations. "Fake medicines kill almost 500,000 sub-Saharan Africans a year: UNODC report", *UN News,* 2023. Retrieved from https://news.un.org/en/story/2023/02/1133062

UNODC. *Transnational Organized Crime in East Asia and the Pacific: A Threat Assessment*, p. 129.

WHO. *Guidelines for the development of measures to combat counterfeit drugs.* Geneva: WHO, 1999.

WHO. *Substandard and Falsified Medical Products.* (WHO, 2018). Available online t https://www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products

WHO. *WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products.* (World Health Organization, Geneva, 2017). www.who.int/medicines/regulation/ssffc/publications/GSMSreport_EN.pdf?ua=1

Wingrove, Patrick. "Rise in reports of fake weight-loss drugs linked to shortage of real thing, WHO says", *Reuters,* January 30, 2024. Online at https://www.reuters.com/business/healthcare-pharmaceuticals/rise-reports-fake-weight-loss-drugs-linked-shortage-real-thing-who-says-2024-01-29/

WIPO, "Committee on Development and Intellectual Property (CDIP)", 2012. http://193.5.93.81/edocs/mdocs/mdocs/en/cdip_9/cdip_9_inf_5.pdf

Wojahn, Patrick L. "A conflict of rights: intellectual property under TRIPS, the right to health, and AIDS drugs." *UCLA Journal of International Law and Foreign Affairs* 6, no. 2 (2001): 463-497.

Wong, Hilary. "The case for compulsory licensing during COVID-19." *Journal of global Health* 10, no.1 (2020): 010358.

World Health Organization. *Global Health Observatory (GHO) data: Neglected Tropical Diseases.* (Geneva: WHO, 2019).

World Health Organization. *WHO Guideline on Country Pharmaceutical Pricing Policies.* (Geneva: WHO, 2015).

World Trade Organization. *Declaration on the TRIPS agreement and public health.* DOHA WTO MINISTERIAL 2001: TRIPS https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

World Trade Organization. *Obligations and Exceptions: Under TRIPS, what are member governments' obligations on pharmaceutical patents?.* Available online at https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm.

World Trade Organization. *Promoting access to medical technologies and innovation Intersections between public health, intellectual property and trade.* WTO, 2013.

World Trade Organization. *Uruguay round Agreement TRIPS: Part II — Standards concerning the availability, scope and use of Intellectual Property Rights*. Available online at https://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm.

Yenet, Aderaw, Getinet Nibret, and Bantayehu Addis Tegegne. "Challenges to the availability and affordability of essential medicines in African countries: a scoping review." *ClinicoEconomics and Outcomes Research* 15 (2023): 443-458.

Yuliani, Evelina, Widodo T. Novianto, and Hari Purwadi. "The Urgency of Law Enforcement of Illegal Medicine Distributions in Indonesia." *Journal of Health Policy and Management* 4, no. 2 (2019): 76-85.

Yuliani, Novianto, and Purwadi. *See also* Yunus, Nur Rohim, et al. "Drug Abuse as an Extra-Ordinary Crime: Some Legal and Political Debates." *Jurnal Scientia Indonesia* 8, no. 1 (2022): 71-88.

Zabyelina, Yuliya, and Stephen Noguera. "Organized Crime and the Pharmaceutical Industry." *The Private Sector and Organized Crime*. Routledge, 2022, pp. 224-241.

Ziavrou, Kalliroi S., Stephen Noguera, and Vassiliki A. Boumba. "Trends in counterfeit drugs and pharmaceuticals before and during COVID-19 pandemic." *Forensic Science International* 338 (2022): 111382.

Ziavrou, Kalliroi S., Stephen Noguera, and Vassiliki A. Boumba. "Trends in counterfeit drugs and pharmaceuticals before and during COVID-19 pandemic." *Forensic Science International* 338 (2022): 111382.

***

The scourge of drug trafficking, that favors violence and sows the seeds of suffering and death, requires of society as a whole an act of courage.

Pope Francis

Acknowledgment
None

Funding Information
None.

Conflicting Interest Statement
The authors state that there is no conflict of interest in the publication of this article.

Generative AI Statement
None

Notification
Starting from the 2024 issue, our journal has transitioned to a new platform for an enhanced reading experience. All new articles and content will now be available on this updated site. However, we would like to assure you that archived issues from 2016 to 2023 are still accessible via the previous site. You can view these editions by visiting the following link: https://journal.unnes.ac.id/sju/jils/issue/archive.