

Committee: World Health Organisation (W.H.O.)

Topic: Addressing the issue of medical black markets

Student Officer: Lenio Bitsopoulou

Position: Deputy President

Topic Introduction

In the words of PhD lead author Michelle Litchman, “In some cases, people have had to go to extreme measures and find a network that can support their healthcare needs.”¹ Medical black markets have recently been evolving and expanding, providing harmful counterfeit medicines and products as an alternative to legitimate, yet costly, medical products. As the price of medical products increases, as seen between January 2022 and January 2023, when the average price increase for prescription drugs was 15.2%, which tallies to about \$590 per drug product², patients cannot seem to afford them, as seen by a 2021 survey by Gallup and West Health, which found that approximately 18 million Americans, or about 7% of U.S. adults, have been unable to pay for at least one prescribed medication in the past three months³. This pushes them to make decisions that put their health at risk, such as purchasing counterfeit medication.

While using medical black markets allows patients to be provided with needed goods and services, such as prescription medications, vaccines, medical devices, or medical information services, that they would be unable to obtain otherwise, black markets in the pharmaceutical industry can further distort prices, increase crime, and reduce government revenue. This promotes illegal business, and unfair trade, creates high interest rates, and damages the patients’ health in the long run.⁴

With collaboration and cross-border commitment to solving the issue, nations can work together to tackle the issue of medical black markets. By addressing the root causes and drivers, as well as the

¹ Healthline. “More People Are Turning to the Black Market for Medication.” *Healthline*, www.healthline.com/health-news/why-people-turn-to-the-black-market-for-medication.

² Bosworth, Arielle. “Changes in the List Prices of Prescription Drugs, 2017-2023.” *ASPE*, 6 Oct. 2023, aspe.hhs.gov/reports/changes-list-prices-prescription-drugs.

³ WestHealth. “18 Million Americans Can’t Afford Needed Medications, Gallup Finds.” *West Health*, 22 Sept. 2021, westhealth.org/news/18-million-americans-cant-afford-needed-medications-gallup-finds/. Accessed 16 July 2024.

⁴ Chemed. “The Black Market: A Necessary Evil in a Broken System.” *www.linkedin.com*, 21 Nov. 2023, www.linkedin.com/pulse/black-market-necessary-evil-broken-system-chemeds-jucie#:~:text=They%20can%20distort%20prices%2C%20red uce.



complications and impacts black medical markets have, the pharmaceutical industry can operate lawfully and ethically, with a supply and demand chain without counterfeit drugs.

Definition of key concepts

Black Market

“Illicit trade in goods or commodities in violation of official regulations.”⁵

Counterfeit Medications

“Medicines that are deliberately and fraudulently mislabeled with respect to their identity and/or source.”⁶

Substandard Medications

“Medical products which are authorized but fail to meet their quality standards or specifications.”⁷

Smuggling

“To import or export secretly contrary to the law and especially without paying duties imposed by law.”⁸

Illicit Drugs

“A drug that is illegal to have (for example, cannabis, heroin, and cocaine), and the non-medical use of legally available drugs such as painkillers and sleeping pills.”⁹

Supply Chain

“The chain of processes, businesses, etc. by which a commodity is produced and distributed.”¹⁰

Organ Trafficking

“The illegal handling of organs.”¹¹

⁵ Merriam Webster. “Definition of BLACK-MARKET.” *Www.merriam-Webster.com*, www.merriam-webster.com/dictionary/black-market.

⁶ World Health Organisation. “Counterfeit Medical Products.” 18 Dec. 2008.

⁷ ---. *Member State Mechanism on Substandard/Spurious/Falsely-Labelled/Falsified/Counterfeit Medical Products*. 20 Mar. 2017.

⁸ Merriam Webster. “Definition of SMUGGLE.” *Www.merriam-Webster.com*, www.merriam-webster.com/dictionary/smuggle.

⁹ Alcohol and other drugs knowledge centre. “Illicit Drugs - General.” *Alcohol and Other Drugs Knowledge Centre*, aodknowledgecentre.ecu.edu.au/learn/specific-drugs/illicit-drugs-general/.

¹⁰ Merriam Webster. “Merriam-Webster Dictionary.” *Merriam-Webster.com*, 2022, www.merriam-webster.com/dictionary/supply%20chain.

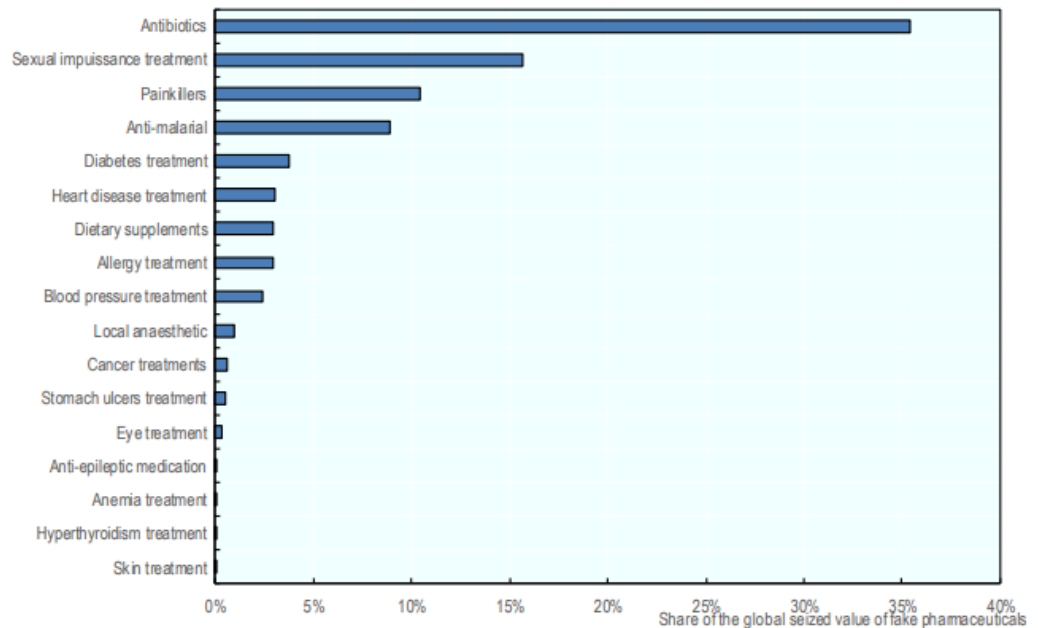
¹¹ Maginn, Susan. “Organ Trafficking Facts.” *The Exodus Road*, 16 Jan. 2023, theexodusroad.com/organ-trafficking-facts/.



Background Information

Counterfeit Medications in Medical Black Markets

Over the period 2014-2016, the use of counterfeit drugs for various kinds of diseases (eg. malaria, HIV/AIDS, and cancer) rose rapidly.¹² As seen in the chart below, data shows that counterfeit antibiotics, lifestyle drugs, and painkillers were the most popular.¹³



Source: OECD/EUIPO database.

Figure 1: Most counterfeit types of pharmaceuticals seized by customs, 2014-2016¹⁴

Profits of Medical Black Markets

Selling counterfeit medications or trafficking organs on medical black markets can be highly profitable and highly attractive to organized crime groups, especially if cheap ingredients are used. According to the Medicines and Healthcare Products Regulatory Agency (MHRA), in the United Kingdom, 100,000 counterfeit pills imported at the price of about GBP 0.25 each were being sold for

¹² OECD/EUIPO. *Illicit Trade Trade in Counterfeit Pharmaceutical Products*. 2020.

¹³ (Ibid)

¹⁴ (Ibid)

up to GBP 20 each, which translates into a profit margin of 7,900%.¹⁵ Another statistic shows that, according to the Human Trafficking Search, the illicit trade in human organs generates significant profits, with estimates ranging from \$840 million to \$1.7 billion annually.¹⁶

Driving factor	Conditions favouring counterfeiting pharmaceuticals	Situation for pharmaceuticals
Market characteristics		
Profitability	High unit profitability and/or large volume	Can be very large, especially if cheap ingredients are used
Market size	Large potential market	Pharma market is large (more than USD 1 trillion) and growing
Brand power	High level of brand recognition	Strong brand power
Production, technology and distribution		
Investment required	Simple, low cost equipment	Cost of making crude fakes can be modest; a pill press may suffice
Technology required	Not sophisticated; easy to acquire	Production technology, packaging and labeling challenges vary; can be easy, or a significant challenge
Logistics	Simple and cheap	Shipping costs are low; free trade zones have facilitated trade in fakes
Marketing and sale of products	Easy to establish/infiltrate distribution channels	Difficult to infiltrate principal supply chains; easier if second tier wholesalers targeted; Internet has facilitated trade in fakes
Ability to conceal operations	Easy to hide illicit operations	Can be easy if operations are on a small scale
Ability to deceive consumers	Easy to deceive consumers	Easy to deceive visually; anti-counterfeiting technology can complicate significantly
Institutional characteristics		
Legal and regulatory framework	Weak laws	Complicated situation in many countries makes it difficult to prosecute
Enforcement	Weak enforcement	Enforcement levels vary across countries; clever counterfeiters often succeed in avoiding enforcement efforts
Penalties	Weak sanctions	Criminal sanctions provided for in many countries; fines are generally a manageable cost of business in many countries

Source: Based on OECD (2008), *The Economic Impact of Counterfeiting and Piracy*, <https://doi.org/10.1787/9789264045521-en>.

Figure 2: Framework for assessing the attractiveness of counterfeiting pharmaceuticals¹⁷

¹⁵ (Ibid)

¹⁶ ACAMS Today. "Organ Trafficking: The Unseen Form of Human Trafficking – Human Trafficking Search." *Human Trafficking Search*, 2018, humantraffickingsearch.org/resource/organ-trafficking-the-unseen-form-of-human-trafficking/.

¹⁷ OECD/EUIPO. *Illicit Trade Trade in Counterfeit Pharmaceutical Products*. 2020.

Impact of Medical Black Markets on Society

Impact of Counterfeit Medicine

Bad-quality medications obtained from medical black markets can affect individuals differently, but what is certain is that people taking counterfeit medicine are putting their lives at risk, especially due to their lack of active and correct ingredients. While many cases of patient harm will most likely not be detected, many examples have been recorded. For example, a recent British survey by Sapio Research and commissioned by the private company INCOPRO proves that almost one-third (32%) of those who have bought one or more counterfeit medicines have suffered a health issue as a result.¹⁸

Impact of Organ Trafficking

Victims of organ trafficking often face severe health issues after surgery due to poor medical care and unsanitary conditions. According to The Exodus Road, an estimated 75% of illegal kidney donors suffer from health problems following surgery.¹⁹

Impact of Illicit Drugs

The negative consequences of illicit drug use affect individuals who abuse drugs, as well as their families and friends, various businesses, and government resources. Only some of the effects include ill health, sickness, and death. NSDUH data indicate that in 2004 over 3.5 million individuals aged 18 and older admitted to having injected an illicit drug during their lifetime. Of these individuals, 14% (498,000) were under the age of 25.²⁰ Children of individuals who abuse drugs often are abused or neglected as a result of the individual's preoccupation with drugs.

¹⁸ INCOPRO. "Counterfeit Products Are Endemic – and It Is Damaging Brand Value." *Corsearch*, 2020, corsearch.com/content-library/ebooks/counterfeit-products-are-endemic--and-it-is-damaging-brand-value/. Accessed 17 July 2024.

¹⁹ Maginn, Susan. "Organ Trafficking Facts." *The Exodus Road*, 16 Jan. 2023, theexodusroad.com/organ-trafficking-facts/.

²⁰ National Drug Intelligence Center. "The Impact of Drugs on Society - National Drug Threat Assessment 2006." *Justice.gov*, National Drug Intelligence Center, Jan. 2006, www.justice.gov/archive/ndic/pubs11/18862/impact.htm.



Case Study: 2008 Blood Heparin Crisis

In 2008, the US pharmaceutical industry faced a crisis because batches of blood thinner heparin were found contaminated. Blood thinner heparin was used to prevent blood clots during medical procedures. The contamination was linked to a Chinese supplier after he introduced a counterfeit ingredient into the drug supply chain.²¹ Read more about the case here: [Heparin crisis 2008: a tipping point for increased FDA enforcement in the pharma sector?](#), [2008 Chinese heparin adulteration - Wikipedia](#), [The heparin recall of 2008](#), [GAO-11-95 Food and Drug Administration: Response to Heparin Contamination Helped Protect Public Health](#)

Case Study: The 2003 Israeli-Brazilian Organ Trafficking Ring

In 2003, authorities uncovered a large organ trafficking ring involving Israeli and Brazilian nationals. The ring was responsible for convincing lower-class Brazilians to sell their kidneys for transplantation in South Africa. The transplants were performed in South Africa, by surgeons and medical professionals who agreed with the illegal operations. After authorities in Brazil suspected 5 people of involvement, in 2010, an Israeli man was sentenced to jail for his role in the trafficking ring, demonstrating the international legal efforts to combat such crimes.²² Read more about the case here: [Israelis Nabbed in Brazil, S. Africa for Organ Trafficking - Haaretz Com](#), [Cops bust human kidney trafficking ring - Dec. 2, 2003](#), [04.30.2004 - UC Berkeley anthropology professor working on organs trafficking.](#)

<u>April 22nd, 1988</u>	The United States enacted the Prescription Drug Marketing Act (PDMA). ²³
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²¹ Rosania, Larry. "Heparin Crisis 2008: A Tipping Point for Increased FDA Enforcement in the Pharma Sector?" *Food and Drug Law Journal*, vol. 65, no. 3, 2010, pp. 489–501, ii, pubmed.ncbi.nlm.nih.gov/24479237/.

²² "CNN.com - Cops Bust Human Kidney Trafficking Ring - Dec. 2, 2003." *Edition.cnn.com*, 3 Dec. 2003, edition.cnn.com/2003/WORLD/americas/12/02/crime.brazil.organs.reut/. Accessed 18 July 2024.

²³ Research, Center for Drug Evaluation and. "Prescription Drug Marketing Act of 1987." *FDA*, 25 Feb. 2022, www.fda.gov/regulatory-information/selected-amendments-fdc-act/prescription-drug-marketing-act-1987#:~:text=The%20PDMA%20was%20enacted%20(1.



<u>1990s (most notable allegation: April 1999)</u>	Allegations in the late 1990s involving the trafficking of organs from Kosovo Albanians during the Kosovo War. ²⁴
<u>May 19th, 1933</u>	The World Health Organization (WHO) adopted resolution WHA46.19, urging member states to implement measures to combat the threat of counterfeit drugs. ²⁵
<u>September 2006</u>	The World Health Organization (WHO) launched the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) to combat counterfeit medications and reduce the risk of medical black markets. ²⁶
<u>2008 (most significant events in January 2008)</u>	Contaminated batches of the blood thinner heparin, produced in China, led to severe negative reactions and deaths in multiple countries. ²⁷
<u>April 23rd, 2010</u>	The Council of Europe adopted the Medicrime Convention, which is the first international treaty criminalizing the production and distribution of counterfeit medical products and devices. ²⁸

²⁴ Fioretti, Julia. "Inquiry Finds "Indications" of Organ Harvesting in Kosovo Conflict." *Reuters*, 29 July 2014, [www.reuters.com/article/world/inquiry-finds-indications-of-organ-harvesting-in-kosovo-conflict-idUSKBN0FY1FJ/#:~:text=BRUSSELS%20\(Reuters\)%20%2D%20An%20EU,lead%20investigator%20said%20on%20Tuesday](https://www.reuters.com/article/world/inquiry-finds-indications-of-organ-harvesting-in-kosovo-conflict-idUSKBN0FY1FJ/#:~:text=BRUSSELS%20(Reuters)%20%2D%20An%20EU,lead%20investigator%20said%20on%20Tuesday).

²⁵ Исполнительный комитет, 134. "Народная медицина: Проект резолюции, предложенный Китаем, Малайзией и Республикой Корея." *Iris.who.int*, 2014, iris.who.int/handle/10665/175799?locale-attribute=en&. Accessed 18 July 2024.

²⁶ World Health Organisation. "Impact." [www.fip.org](http://www.fip.org/www.fip.org/impactglobalforum/#:~:text=The%20International%20Medical%20Products%20Anti).

²⁷ Wikipedia. "2008 Chinese Heparin Adulteration." *Wikipedia*, 31 Jan. 2024, en.m.wikipedia.org/wiki/2008_Chinese_heparin_adulteration. Accessed 17 July 2024.

²⁸ "The MEDICRIME Convention." *MEDICRIME Convention*, www.coe.int/en/web/medicrime/the-medicrime-convention.



<p><u>October 5th, 2015</u></p>	<p>Interpol conducted Operation Pangea VIII, involving 115 countries to combat online sales of counterfeit and illicit medications and medical devices.²⁹</p>
<p><u>2019-2021</u></p>	<p>Numerous reports emerged of the illegal selling of counterfeit or unauthorized COVID-19 vaccines.³⁰</p>
<p><u>2021</u></p>	<p>Interpol's Operation Pangea XIV targeted illegal online pharmacies selling counterfeit and unauthorized medicines by involving law enforcement agencies globally and led to the seizure of millions of counterfeit medical products.³¹</p>

Major countries/ organizations and alliances

China

China is a crucial manufacturer of pharmaceutical products, however, also a significant source of counterfeit medications. Read more here: [Pharmaceuticals - China | Statista Market Forecast](#), [Pharmaceutical industry in China - Wikipedia](#), [The next phase: Opportunities in China's pharmaceuticals market](#).

²⁹ Interpol. "INTERPOL-Coordinated Operation Strikes at Organized Crime with Seizure of 20 Million Illicit Medicines." *Www.interpol.int*, www.interpol.int/en/News-and-Events/News/2015/INTERPOL-coordinated-operation-strikes-at-organized-crime-with-seizure-of-20-million-illicit-medicines#:~:text=Operation%20Pangea%20VIII%20was%20the. Accessed 18 July 2024.

³⁰ "COVID-19 Vaccine Race: The Black Market Opportunity." *IJSS*, www.ijss.org/en/online-analysis/online-analysis/2021/02/covid-19-vaccines-black-market/. Accessed 18 July 2024.

³¹ Interpol. "Pharmaceutical Crime Operations." *Www.interpol.int*, www.interpol.int/en/Crimes/Illicit-goods/Pharmaceutical-crime-operations#:~:text=Since%202008%2C%20Operation%20Pangea%20has. Accessed 16 July 2024.



India

According to Outsourcing Pharma in 2012, 75% of counterfeit medications supplied worldwide had some origins in India³², meanwhile, the Associated Chambers of Commerce and Industry of India (ASSOCHAM) wrote in the paper “Fake and Counterfeit Drugs In India –Booming Biz” that illicit drugs constitute \$4.25 billion of the total \$14–17 billion of the domestic drug market, proving around 25% of India's medications are counterfeit.³³ Read more here: <https://web.archive.org/web/20200523071312/https://www.downtoearth.org.in/news/fake-drugs-constitute-25-of-domestic-medicines-market-in-india-assochem-45393>, [Indian-made cold syrup sent to Iraq contains poison, test shows | India – Gulf News](#).

Pakistan

The Pakistan fake medicine crisis in 2012 revealed the large production of counterfeit medications in Pakistan. Read more here: [Fake medicine: Unofficial death toll reaches 112](#), [Pakistan’s counterfeit medicine problem](#), [About: 2012 Pakistan fake medicine crisis](#).

United States of America

The United States is a large market for both legitimate and counterfeit medications. Read more here: [Comparing Global Pharmaceutical Markets: US, UK, and China](#), [Snapshot of the American Pharmaceutical Industry | Executive and Continuing Professional Education](#).

United Nations Office on Drugs and Crime (UNODC)

The United Nations Office on Drugs and Crime (UNODC) addresses issues regarding recreational drugs, including counterfeit medications, substandard medications, and illicit drugs. Read more here: [Falsified medical products](#).

World Health Organisation (WHO)

The World Health Organisation (WHO) provides leadership on the pharmaceutical supply chain and addresses issues regarding recreational drugs, including counterfeit medications, substandard medications, and illicit drugs. Read more here: [Substandard and falsified medical products](#)

³² outsourcing-pharma.com. “New Counterfeit Report Highlights Worrying Trends.” *Outsourcing-Pharma.com*, 7 Nov. 2007, www.outsourcing-pharma.com/Article/2007/11/07/new-counterfeit-report-highlights-worrying-trends.

³³ Singh, Jyotsna. “Fake Drugs Constitute 25% of Domestic Medicines Market in India: ASSOCHAM.” *Web.archive.org*, 23 May 2020, web.archive.org/web/20200523071312/www.downtoearth.org.in/news/fake-drugs-constitute-25-of-domestic-medicines-market-in-india-assochem-45393. Accessed 16 July 2024.



Previous attempts to solve the issue

Falsified Medicines Directive (FMD) in the European Union (EU)

Under the FMD, all packs of prescription medicines should have an anti-tampering device (ATD) and unique identifier (UI) to enhance the security of the manufacturing and delivery of medicines in Europe, as well as prevent counterfeit medicines from entering the supply chain.³⁴ Read more here: [Falsified Medicines Directive implementation toolkits - NHS England Digital](#).

Operation Pangea by Interpol

Operation Pangea dismantles criminal networks and reduces the risk these crimes pose to public health by collecting data and disseminating intelligence, coordinating transnational law enforcement operations, supporting multi-agency task forces to improve cooperation between police, customs, regulatory bodies, and the private sector, and raising public awareness of pharmaceutical crime and helping consumers to make informed choices.³⁵ Read more here: [Pharmaceutical crime operations](#).

Possible solutions

International Framework Alignment

Strengthening and aligning regulatory frameworks and implementing strict policies, laws, and regulations that are consistent across member states is a method of combating medical black markets. Strengthening regulations internationally directly combats medical black markets by establishing consistent international standards, enhancing enforcement, and improving cross-border cooperation, which increases the likelihood of detection of medical black-market products and the people in charge of distributing them.

³⁴ NHS England. "Falsified Medicines Directive Implementation Toolkits." *NHS England Digital*, digital.nhs.uk/services/falsified-medicines-directive-fmd#fmd-overview. Accessed 16 July 2024.

³⁵ Interpol. "Pharmaceutical Crime Operations." *www.interpol.int*, www.interpol.int/en/Crimes/Illicit-goods/Pharmaceutical-crime-operations#:~:text=Since%202008%2C%20Operation%20Pangea%20has. Accessed 16 July 2024.



Improving Access to Legitimate Medications

Enhancing access to legitimate medicines is another solution in combating medical black markets. Nations could collaborate with pharmaceutical companies to make essential medicines more affordable and can significantly reduce the demand for cheaper counterfeit alternatives. By lowering costs and increasing the availability of authentic medications, patients are less likely to turn to illicit sources. However, issues arise during the implementation of such a solution, as lowering the costs of legitimate medicines, consequently, reduces the income of large pharmaceutical businesses.

Developing Support Systems for Patients

Developing rapid response mechanisms is essential in combating the rapid increase of counterfeit drugs. By establishing systems that can respond quickly to incidents involving fake medications, authorities can mitigate harm more effectively. This can happen through advanced technologies and strong and vigorous monitoring systems that ensure timely identification and removal of dangerous products from the market.

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