

Forum: Legal Committee (GA6)

Issue: Developing measures to eradicate the manufacturing and trafficking of counterfeit medicines

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INTRODUCTION

The issue of manufacturing and trafficking of counterfeit medicines has been troubling the public health systems and the economy of both developed and developing countries for the past decades. The consumption of such medicines has caused thousands of deaths worldwide. Although in countries, where the regulatory bodies are weaker, the problem seems to be more widespread, its lethal consequences have reached several other countries with stricter regulations.

Although the problem itself existed for many decades, it was brought to the international eye only after the Nairobi conference in 1985.

Under Article 25(1) of the United Nations Universal Declaration of Human Rights (1948), "Everyone has the right to a standard of living adequate for the health and well-being of himself and his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control."¹²



Inside a street market's special section for falsified drugs.

The World Health Organization (WHO) has found that approximately 1 out of 10 medicines in less economically developed countries is falsified. These drugs may contain the false amount of active ingredient, no active ingredient at all or even the wrong active ingredient. The consumption of counterfeit medical products can lead to serious health problems as well as high antimicrobial resistance. Each year, more than 250,000 people lose the battle to malaria, pneumonia and other common illnesses in less economically developed countries (LEDCs) after being treated with falsified medicines.³ With that in mind, the effectiveness of the current legislation is to be questioned and possible ways to improve it have yet to be found.

¹ Universal Declaration Of Human Rights

<https://www.un.org/en/universal-declaration-human-rights/>

² image source: Fighting the Spread Of Fake Drugs in Africa: Dw: 10.01.2018

Deutsche Welle - <https://www.dw.com/en/fighting-the-spread-of-fake-drugs-in-africa/a-42100713>

³ "It's Time to Stop Murder by Counterfeit Medicine." STAT, 8 May 2019, www.statnews.com/2019/05/07/stopping-murder-counterfeit-medicine/.

DEFINITION OF KEY TERMS

Counterfeit medicines

The European Medicines Agency defines the term as “A medicine made by someone other than the genuine manufacturer, by copying or imitating an original product without authority or rights. Counterfeit medicines infringe trademark law.”⁴

Falsified

A falsified medicine is an altered medicine produced in order to mislead the public.

Substandard

A medical product that does not meet the criteria concerning the quality standards and/or specifications.

Trafficking

Trafficking refers to trading or dealing in illegal substances. This term is commonly used in relation to human trafficking for the purpose of forced labor and sexual exploitation but can also apply to trading of counterfeit medicines.

Fraud

Criminal behavior for the purpose of obtaining money and/or property.

Antimicrobial resistance (AMR)

AMR happens when microorganisms develop the ability to hinder and/or defeat the antibiotic drug designed to kill them. As a result antibiotic treatments become more and more ineffective. Thus, antibiotic-resistant infections can be very hard to treat, if not impossible.⁵

Manufacturing

The production of goods using machinery.

BACKGROUND INFORMATION

The access to proper medication is a human right and should not be taken for granted. Especially at times as such, during the global pandemic, the need for proper medication around the world is constantly increasing. In less developed regions in Africa and Asia, which constantly suffer from wide-spread diseases, the need for proper antibiotics, vaccinations and generally medicines is greater than ever before. As demand is very high worldwide, the prices of proper medications increase, thus limiting the access of the lower socioeconomic classes

⁴ <https://www.ema.europa.eu/en/glossary/counterfeit-medicines>

⁵ <https://www.cdc.gov/drugresistance/about/>



Geographic Distribution of Reported Pharmaceutical Crimes.

to them. Subsequently, the cheaper alternatives, most of which are falsified, substandard or counterfeit medicines, become more and more popular. Most of these medicines come from manufacturing facilities in China and India. The main reason for this is the lack of legislation when it comes to the production of medical products.

These drugs follow illicit routes with their destination being several underdeveloped regions in the African continent or other regions around the globe. There, they are distributed across unregulated street markets or make their way into the online illegal medicine market. People can then buy these drugs at extremely low prices and most of the time they are not even aware that they are purchasing fake medications.⁶

Another reason behind the rapidly increasing counterfeit drug industry is the social stigma one might face, when seeking help by licensed professionals, especially when it comes to matters like eating disorders (weight loss or gain), any type of sexual dysfunction and erection problems, people tend to feel ashamed of consulting a professional. These insecurities have been caused by society itself and as a result patients turn to illegal medicines instead of speaking out.

The aforementioned reasons and many others make the manufacturing and trafficking of counterfeit medicines an international problem mainly affecting less economically developed countries without turning a blind eye to more economically developed ones.

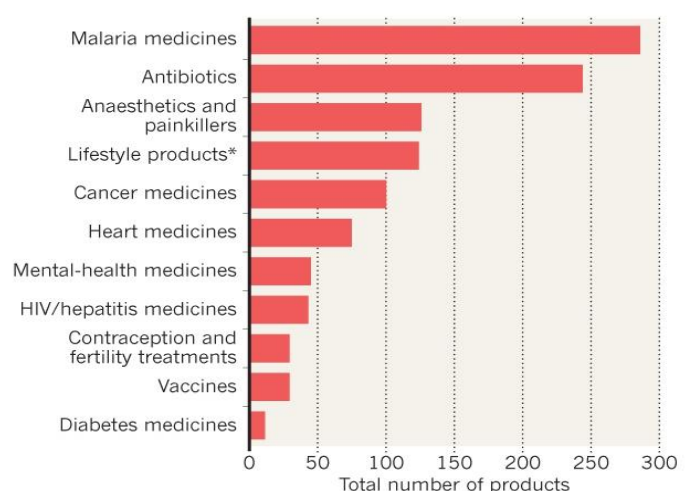
Health risks

For a medicine to be effective and not cause any serious side effects to the patient the right amount of active ingredients should be ensured; which does not apply to substandard medicines. So patients taking substandard or fake medication are putting their lives in extreme danger.

One health problem that can occur after the consumption of substandard medication is mass poisoning. A typical example is the death of 84 Nigerian children back in 2008 from total kidney failure after the consumption of industrial solvent diethylene glycol in teething syrup. In addition, fake medicines increase antimicrobial resistance (AMR) making chronic diseases harder to treat, thus progressing and having lethal consequences.

Pakistan fake medicine crisis

In early December 2011, hospitalized patients across the city of Lahore started having some extreme symptoms caused by taking locally-manufactured cardiovascular medication distributed for free by the Punjab Institute of Cardiology in Lahore, as it was discovered later on by a team of doctors.⁷ These health problems showed early their lethal



⁶ Image source: "The Real Truth On Counterfeits" <http://www.onlinemarketing-trends.com/2011/0/>

⁷ "Combating Counterfeit Drugs: Building Effective International Collaboration, 16-18 February 2006 - Rome, Italy." World Health Organization, www.who.int/medicines/counterfeit_drugs/en/

consequences and only a month after they had been noticed 25 people had already passed away and thousands were put into emergency rooms (ERs).⁸

More specifically, these substandard medicines caused antimicrobial resistance, since their active substance deposited in the patients' bone marrow. Thus the white blood cells were unable to be produced causing a series of symptoms that led to the death of 112 people already suffering from cardiological diseases.

These drugs, nevertheless, had been distributed to more than 40,000 people before the government and health officials were made aware of their side effects. The people affected the most by these medicines belonged to the lower socioeconomic classes, since these drugs were cheaper than the original ones making them more popular along these classes.

Current Legislation

Directive 2011/62/EU⁹

In order to protect the wider public from the entry of counterfeit medicines into supply chains, this Directive imposed a series of stricter measures some of which include: a more consistent record-keeping for wholesale distributors, a common identification logo put on legal online pharmacies to distinguish them from illegal ones. Most importantly, the EU Directive enforced stricter inspections on the producers of active pharmaceutical ingredients.

Medicrime Convention

The Medicrime Convention was the first convention to establish an international instrument in the criminal law field on counterfeiting of medical products and similar crimes involving threats to public health. It criminalized the manufacturing of counterfeit medical products, supplying, offering to supply and illicit 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 all the relevant requirements. Moreover, a legal framework is provided to ensure national and international cooperation. The convention was put into force in 2016 and consists of 32 signatory parties around the world.

MAJOR COUNTRIES AND ORGANIZATIONS INVOLVED

India

It is estimated that around one in four medicines in India is either falsified or substandard. This proportion remains high mainly because of the lack of national legislation and laboratory facilities for the conduction of purity checks and subsequently the inadequate staff appointed to inspect the quality of the drugs. For India, however, substandard medicines constitute a bigger problem than the falsified ones. Nevertheless, both pose a huge risk to people's health. According to a study conducted in 2012 by Outsourcing Pharma, 75% of the counterfeit drugs distributed that year had

⁸ "Health Agency Reveals Scourge of Fake Drugs in Developing World." *World Genetics*, 12 Aug. 2019, www.worldgenetics.org/16454-2/

⁹ EUR-Lex — Access to European Union Law — Choose Your Language, eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:174:0074:0087:EN:PDF

come from India. Lastly, an additional factor that contributes to India's 1 billion fake medicines industry is the lack of public awareness.

In 2003, the Indian government planned to make the trafficking of fake drugs a capital punishment offense. In 2011, in an unprecedented decision, the Bombay High Court struck down the mandatory death penalty for drug offences, becoming the first Court in the world to do so.¹⁰ This decision was taken under the section 31A of the Narcotic Drugs and Psychotropic Substances Act, 1985 (NDPS Act).

Côte d'Ivoire (Ivory Coast)¹¹

Being a less economically developed country, Cote d'Ivoire faces several issues with trafficking of counterfeit drugs. Nevertheless, from 2017 to 2018, nearly 400 tons of falsified drugs were seized. The city mainly involved is "Abidjan" where most counterfeit goods are being sold. Additionally, it is estimated that 30% to 40% of medicines are to be purchased in street markets, as they are way cheaper than the original ones. Ivory Coast's pharmaceutical industry has lost over \$170 million to falsified medicines. Research by WHO shows 42% of the reported fake drugs originate in Africa. Finally, it should be noted that in August 2019, Côte d'Ivoire became a member of the "Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health"¹², by signing the convention.



Woman selling counterfeit drugs in one of Abidjan's street markets.

China

China as well as India has a leading role in the issue of counterfeit, substandard and falsified medicines. Just like India, the inadequate regulations seem to be the main cause behind this widespread problem. The most recent act of the Chinese Food and Drug Administration should be noted with satisfaction, namely the release of a draft regulation banning online selling of prescription drugs or drugs that allegedly have quality problems. Nevertheless, the counterfeit medicines manufactured in China either make their way to the street markets of Africa or are being distributed to Chinese street markets and illegal online stores. Chinese counterfeit medical products have been found to contain pollen, chalk and many more non-effective ingredients. So it is not

¹⁰ "Indian Court Overturns Mandatory Death Penalty for Drug Offences - First in the World to Do So!" *International Drug Policy Consortium*, 2020, idpc.net/it/alerts/2011/08/india-death-penalty.

¹¹ image source: *ResearchGate*, 1 Apr. 2016, www.researchgate.net/figure/Women-sell-smuggled-counterfeit-medicine-on-the-Adjame-market-in-Abidjan-Ivory-Coast_fig1_237822105

¹²

rm.coe.int/CoERMPublicCommonSearchServices/DisplayDCTMContent?documentId=090000168008482f.

curious that tens of thousands of people lose their lives every year in China by fake medicines. Counterfeit medicine producers usually face minor fines from 17\$ to 507\$.¹³

World Health Organization (WHO)

Founded in 1948, the WHO's main objective is the attainment of the highest possible level of health by all peoples. Bearing that in mind, WHO has provided technical support to more than 100 cases since 2017 and issued about 20 reported alerts concerning medical products. In cooperation with Interpol, they seized more than 20 million counterfeit medicines in 2009. This operation took place in the Southeast Asian region with a special emphasis on China. The WHO itself has a working force of 550 employees in 140 member states solely focusing on reporting substandard medicines. One of WHO's most important projects in order to tackle the issue was the launching of the Global Surveillance and Monitoring System,¹⁴ which, through encouraging the reporting of incidents, led to a more effective assessment of the problem.

International Institute of Research Against Counterfeit Medicines (IRACM)

The IRACM was founded in 2010 as a response to the ever-growing problem of counterfeit medicines. It is an independent international organization solely focused on combating the rising threat of the manufacturing and distribution of fake medical products. Their success is built on raising awareness, educating and training both the public and their medical staff. Actions taken by IRACM are considered complementary to these of the WHO and Interpol. Lastly, the IRACM, with the help of national organizations and/ or the governments, has led operations to more than 100 countries and has seized life-threatening pills and other types of fake medicines.¹⁵

The International Criminal Police Organization (INTERPOL)

Interpol has launched several successful operations to tackle the manufacturing and trafficking of counterfeit medicines, the largest and the most recent one being Operation Pangea which started in 2008. Since its launch in 2008, the Operation has removed more than 105 million units (pills, ampoules, sachets, bottles and so on) from circulation and made more than 3,000 arrests.

TIMELINE OF EVENTS

DATE	DESCRIPTION OF EVENT
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¹³ China's Counterfeit Medicine Trade Booming Katie Lewis - <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2774384/>

¹⁴ "WHO Global Surveillance and Monitoring System." *World Health Organization*, www.who.int/medicines/regulation/ssffc/surveillance/en/

¹⁵ A map of the said operations can be found here: <http://www.iracm.com/en/geographic-observatory/seizures-map/>

1948	United Nations Universal Declaration of Human Rights.
3 December 1976	The International Covenant on Economic, Social and Cultural Rights (ICESCR) was put into force.
1979	Iran hostage crisis.
1985	Nairobi Conference.
2008	Launch of Operation Pangea.
2010	The International Institute of Research Against Counterfeit Medicines (IRACM) was created.
May 2010	The 63rd WHO meeting focused on falsified medicines.
8 June 2011	Directive 2011/62/EU of the European Parliament and the council was published.
16 June 2011	Indian Court struck down mandatory death penalty for drug offences.
1 October 2011	Anti-Counterfeit Trade Agreement (ACTA) was signed.
December 2011 - January 2012	Pakistan fake medicine crisis.

1 January 2016	Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health was put into force.
15 May - 17 June 2017	Launch of Operation Heera.

RELEVANT UN RESOLUTIONS, TREATIES AND EVENTS

Follow-up on strengthening the systems of control over chemical precursors and preventing their diversion and trafficking (A/RES/59/162), 20 December 2004¹⁶

This United Nations General Assembly (UNGA) resolution was originally adopted by the third committee of the GA. Emphasis should be given to the first clause, which asks for cooperation between nations via data-sharing of international trafficking as a means to prevent future incidents.

United Nations Convention against Transnational Organized Crime and the Protocols Thereto¹⁷

This convention was put into force in 2003 and counts 147 signatories. It is the first international convention to fight organized crime, trafficking and terrorism. This piece of legislation sets the ground for the development of frameworks regarding minimization and persecution of the illegal counterfeit drug trade around the world.

Strengthening international cooperation and comprehensive regulatory and institutional frameworks for the control of precursors used in the illicit manufacture of narcotic drugs and psychotropic substances, 21 March 2019 (A/RES/62/1)¹⁸

This resolution adopted by the Economic and Social Council (ECOSOC) aims to confirm that member states must reimburse the operations and organizations that combat counterfeit drugs through their continuous contribution to the efforts made by the International Narcotics control board.

Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover, on access to medicines¹⁹

This UNGA report, inter alia, recalls the legal obligation of States to provide their people with adequate healthcare services, under article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR).

¹⁶ "A/RES/59/162 - E - A/RES/59/162." *ESubscription to United Nations Documents*, undocs.org/A/RES/59/162

¹⁷ *United Nations Office on Drugs and Crime*, www.unodc.org/documents/treaties/UNTOC/Publications/TOC%20Convention/TOCebook-e.pdf

¹⁸ <https://undocs.org/E/CN.7/2019/L.2/Rev.1>

¹⁹ "Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, Anand Grover." *United Nations Digital Library System*, digitallibrary.un.org/record/652915?ln=en.

Unfortunately, the sixth committee of the General Assembly has not released any decisions or resolution on the matter for the past eight years.

PREVIOUS ATTEMPTS TO RESOLVE THE ISSUE

There have been several attempts on a national level by member states with the help of Non-Governmental organizations (NGOs) and/or Intergovernmental Organizations (IGOs). However, the attempts listed below are the most successful operations on an international level.

Operation Heera by Interpol

Launched in 2017, it aimed to uncover crimes regarding counterfeit goods in Africa. 1150 law enforcers in Benin, Burkina Faso, Côte d'Ivoire, Mali, Niger, Nigeria and Togo were involved in the operation. After one month, 41 million pills and thousands of packs of illicit medical products were seized. It is estimated that all these fake products had a value of approximately 22 million USD. In addition, 150 individuals were arrested and/or put under close investigation due to their unlawful actions.²⁰



Aftermath of the operation Pangea XIV in 2020

Operation Pangea by Interpol²¹

In 2008, Interpol launched the Operation Pangea in order to disrupt the online sale of counterfeit drugs. The operation also functioned as a means of raising awareness of the prospected risks one could face when purchasing medicines from unauthorized websites, as well as on the online counterfeit market as a whole. Up until now, there have been over 105 million falsified drug removals from circulation, 82.000 websites selling such drugs shut down, and over 3.000 arrests.²² With this operation however, several criminal groups behind the trafficking of medicines have started taking more precautions than ever before. These include, inter alia, the following two: avoiding complicated shipping routes, thus detection, and changing the package of the drugs so as not to look too "suspicious" on the outside.

²⁰ "Hundreds of Tonnes of Illicit Medicines Seized in African Operation." *INTERPOL | The International Criminal Police Organization*, www.interpol.int/en/News-and-Events/News/2017/Hundreds-of-tonnes-of-illicit-medicines-seized-in-African-operation

²¹ Image source: "Illicit Online Pharmaceuticals: 500 Tonnes Seized in Global Operation." *INTERPOL | The International Criminal Police Organization*, www.interpol.int/News-and-Events/News/2018/Illicit-online-pharmaceuticals-500-tonnes-seized-in-global-operation

²² "Operation Pangea – Shining a Light on Pharmaceutical Crime." *INTERPOL | The International Criminal Police Organization*, www.interpol.int/en/News-and-Events/News/2019/Operation-Pangea-shining-a-light-on-pharmaceutical-crime

Iran hostage crisis of 1979

After the 1979 US Embassy hostage crisis in Tehran, the UN Security Council, the European Union and most importantly the United States of America imposed economic sanctions targeting Iran's nuclear activity. These sanctions nevertheless resulted in crucial domestic shortages on original medication. As a result, over 6 million Iranian citizens faced limited treatment while the health sector was forced to turn to falsified and less expensive medications.²³

POSSIBLE SOLUTIONS

Lowering the costs of the original medicines

As the problem is more widespread in Less Economically Developed Countries (LEDCs), where a big part of their population lives in poverty, it is only logical that this part does not have the wherewithal to pay for original medicines. Governments should find ways to help the ones in need of healthcare and provide them with the necessary means to access healthcare institutions. Lowering the cost of the original medicines would discourage people from seeking cheaper and therefore riskier alternatives.

Raising awareness

Governments should raise awareness among their people on how to identify falsified medicines as well as avoiding them in the first place. So people will have the needed knowledge to identify them and not to consume. The consumers' awareness of avoiding counterfeit drugs would reduce a lot the income of illegal drug manufacturers making this sector of the black economy unattractive for investment.

Identification methods

As mentioned before, in order to drastically reduce the consumption of counterfeit medicines, people should be able to recognize them before being tricked into buying and consuming them. Member states alongside non-governmental organizations (NGOs) should code user-friendly identification apps. These would be able to scan the barcode and/or a set verification sticker provided by the Ministry of Health or other intergovernmental organizations of each country.

International legal framework

A more permanent solution is the establishment of an international legal framework. The existing legislation seems to have many gaps since the crime rates on the counterfeit medicine field increase every year. In addition, given the constant "improvement" of organized crime, the existing legislation needs to be significantly upgraded. As mentioned, the Legal Committee has not released any resolutions on the topic since 2014. So adding this topic into their agenda will only open the way to finding more solutions.

²³ "Addressing the Impact of Economic Sanctions on Iranian Drug Shortages in the Joint Comprehensive Plan of Action: Promoting Access to Medicines and Health Diplomacy." *Globalization and Health*, globalizationandhealth.biomedcentral.com/articles/10.1186/s12992-016-0168-6.

International cooperation

This issue affects most countries in the world. So the best way to deal with this is through cooperation. A shared database —accessible to every member state and run by INTERPOL and/or the WHO— recording the deaths caused by counterfeit drugs by country as well as reporting suspicious network activity in this field would strengthen the international cooperation and lead to better relations between countries. This database could also work to identify multiple time offenders in the field of manufacturing and trafficking of fake drugs.

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