Enforcement Action against Counterfeiting of Medicine

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Abstract

Counterfeiting is a growing global problem and mostly well-known products and essential things are targeted by counterfeiters for imitation identically or resemblance of another thing with the intention to deceive consumers. In the counterfeit goods, counterfeit medicine is a direct threat to health. Genuine drug is vital to lives but dangerous drugs such as fake drug, adulterated drug and deteriorated drug are increasing in the market, particularly in the lack of regulatory control. It is therefore important to standardize the quality of drug and to take action effectively on the pharmaceutical counterfeiting; especially in COVID-19 pandemic situation medicine have been played a crucial role to be genuine in saving lives. Many countries promulgated national law including enforcement measures to control the drug safety. Under the law the drug counterfeiters should be punished with deterrent sanctions if making, selling or distributing the counterfeits. In order to be effective law enforcement activities, cooperation with the relevant agencies whether local, regional or global is crucial as it is related to a transnational crime and a sophisticated nature in tackling.

Key words: counterfeiting, drug, enforcement, safety, combat, cooperation

Introduction

This research aims to analyse the fight against counterfeit medication how to be enforced by law in both local and international areas. Any product can be imitated and counterfeit medicine is one of the most dangerous things in threatening to human life. To combat drug counterfeiting, law enforcement action is a tool and needs to be efficient. Firstly, this research examines the nature of pharmaceutical counterfeiting that constitutes a counterfeit medicine and how to define it. In most countries, safety of drug is controlled by the regulatory bodies. Furthermore, this work explores the conduct of law enforcement authorities and the sanctions against counterfeiting of medicine. Finally, this analysis provides the reasons why the cooperative activities both local and international are important to combat medicine counterfeiting since it is becoming a global issue involving transnational crime.

Material and Methods

In order to complete this research, a systematic search based on the statutory, case study, international instruments, books and relevant information from the reliable sources.

Pharmaceutical Counterfeiting

Product imitation is one which is produced with the intent to deceptively into origin, authenticity or effectiveness. It is important to recognize that counterfeiting is an economic crime, comparable to theft. According to the OECD data, "illicit trade in counterfeit and pirated goods is a significant and growing problem having risen from 2.5% of world trade in 2013 to 3.3% in 2016."[1] Pharmaceutical counterfeiting is included in the focus of counterfeit activities and it is the worst form in the fake products. The latest edition of the operation by INTERPOL reported "an increase of about 18 per cent in seizures of unauthorized antiviral medication, and an increase of more than 100 per cent in seizures of unauthorized chloroquine (an antimalarial medication), which could also be connected to the COVID-19 outbreak."[2]

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[1] https://brandprotection.sicpa.com/news/trade-in-counterfeit-pharmaceutical-products-a-2020-report/#:~:text=The%20Organisation%20for%20Economic%20Cooperation%20and%20Development%20%28,counterfeit%20and%20pirated%20goods%20is%20a%20significant%20

[2] https://www.interpol.int/News-and-Events/News/2020/Global-operation-sees-a-rise-in-fake-medical-products-related-to-COVID-19

"According to INTERPOL, overall, authorities seized around 4.4 million units of illicit pharmaceuticals worldwide."[3]

Figure- 1[4]

"The rise of digital channels facilitating the sale and purchase of consumer goods has fueled a rapid increase in trade of counterfeit products around the world."[5] Usually, counterfeit goods are made by forging well-known products in all details of construction and appearance so as to deceive customers into thinking that they are getting genuine goods. As the nature of counterfeiting, it is related to the infringement of intellectual property rights. The below pictures show that fake goods are copied from the genuine one identically or resemble to the real thing.

Photos from Google image

Table 1[6] - Types of counterfeiting

Term	**Definition**
Adulterate	A component of the legitimate finished product is fraudulent
Tamper	Legitimate product and package are used in a fraudulent way
Over-run	Legitimate product is made in excess of production agreements
Theft	Legitimate product is stolen and passed off as legitimately procured
Diversion	The sale or distribution of legitimate product outside of intended markets
Simulation	Illegitimate product is designed to look like but not exactly copy the legitimate product
Counterfeit	All aspects of the fraudulent product and package are fully replicated

[3] *Ibid*
[4] https://www.oecd.org/newsroom/trade-in-fake-goods-is-now-33-of-world-trade-and-rising.htm
[5] https://www.forbes.com/sites/forbestechcouncil/2020/03/17/the-counterfeit-problem-and-how-retailers-can-fight-back-in-2020/?sh=631aacbe1f32
[6] https:// crimesciencejournal.biomedcentral.com- 3 (biomedcentral.com)

It should be noted that "in each case, fraudsters may not be following the regulatory definitions of Good Manufacturing Practices (GMPs), Good Agricultural Practices (GAPs), or Good Hygiene Practices (GHPs)."[7]

"There are different kinds of counterfeiting of pharmaceutical products, depending on the 'scruples' of the counterfeiter, so that it can involve just packaging or the manufacturer of a totally fake product.'[8]

Another important distinction for each type of product counterfeiting is that products could be deceptive or non-deceptive. Deceptive counterfeit products are presented in the marketplace as real with the intent to swindle the consumer. Non-deceptive counterfeit goods existed in the market as counterfeit or fraudulent with no intent to deceive the purchaser. These are marketed to consumers who seek imitated or copied products such as apparel and luxury goods. It is significant that no consumer wants to use unsafe medicine such as fake drug or defective medicine which are harmful to health.

"All counterfeit drugs are illegal, whether they are harmless or not. It is just plain criminal to manufacture these fake products."[9] With growing technological sophistication, counterfeiters are often able to make fake medicine look almost identical to authentic ones. It is difficult to differentiate between the original and the fake one. Consumers may not know that the medicine they have purchased are counterfeits. Regarding drug counterfeiting cases, all related activities should be considered as a crime because it is a real danger to public health.

Important Definitions concerning Counterfeit Medicine

Although most of counterfeit products are made by using identical or similar trademark used by another, some counterfeiting activities are related to the fraudulent acts on source and get-up.

Under Article 51 of the TRIPS Agreement, WTO member States oblige to prevent counterfeit trademark and pirated copyright goods from entering national markets. The word 'counterfeit' focuses on infringement of trademark and copyright.

WHO says that "a counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, with active ingredients, with insufficient active ingredient or with packaging."[10] According to the definition, the key factors can be said that intention to deceive and intellectual property rights are generally favourable. "Soon after, some developing country WHO members and health activists became concerned that the word was being used to confuse public opinion of legal, good quality generic drugs."[11] Medicine whether branded or generic are not spared to be forged by counterfeiters.

In the fight against counterfeit drug, it is important to understand that the nature of the fraud and it is not merely related to IP infringement. In addition to the intellectual property rights infringements, counterfeiters put labels of firms which may not even exist on the packaging of their drug products, so as to bypass the penal action by law enforcement agencies. Another ploy is to use the name of one drug with the label of another drug in the

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[7] https:// crimesciencejournal.biomedcentral.com- 3 (biomedcentral.com)

[8] Albert I. Wertheimer and Perry G. Wang, Counterfeit Medicines Volume I: Policy Economics and Countermeasures, ILM Publication, 2012, p.45.

[9] *Ibid*, p.1.

[10] Guidelines for the Development of Measures to Combat Counterfeit Drugs, Department of Essential Drugs and Other Medicines, WHO, 1999, p.8.

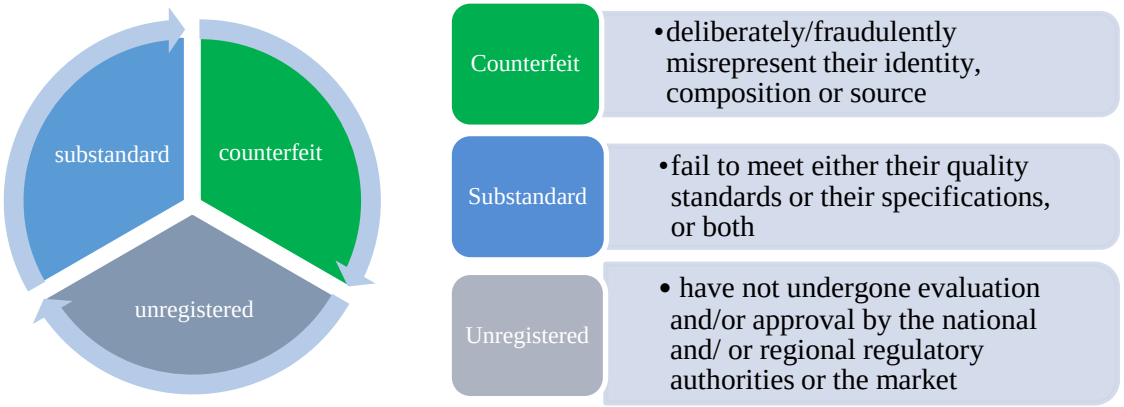
[11] https://www.ip-watch.org/2017/01/30/board-agrees-drop-word-counterfeit-30-years/

same class which is cheaper. Drug counterfeiting is related to quality which is important to human health.

In wealthy countries like the UK with strong regulatory frameworks, counterfeits are likely to account for 1% of the total medicines market, but as estimated, 50% of drugs sold online are fake drugs.[12] Counterfeit drugs account for about 30-45% of total drug sales in developing countries.[13] In developing countries, life-saving and chronic drugs for deadly conditions like malaria, HIV, tuberculosis, hypertension, acid reflux, diabetes and hyperlipidemia are main targets for drug counterfeiters. In developed countries, the target drugs are newer ones with active patents that tend to be expensive. Examples are lifestyle drugs such as Viagra, psychiatric drugs, cancer drugs, steroids, hormones and monoclonal antibodies.[14]

"A unified terminology common to all Member States and other stakeholders is crucial to the success of the Member State Mechanism and the broader global effort to ensure safe supply chains for medical products. For example, clear, standardized definitions enable better data collection and analysis. Resolving the definition issue was a major achievement of the Mechanism."[15]

"WHO used the term "substandard/ spurious/ falsely-labeled/ falsified/ counterfeit medical products" (SSFFC). The WHO Member State mechanism on SSFFC medical products was tasked with revising these definitions to ensure that they were based on a public-health perspective, with no account taken of intellectual property concerns. Based on their deliberations, the World Health Assembly governed by WHO, adopted the following definitions: **Substandard medical products** called "out of specification", these are authorized medical products that fail to meet either their quality standards or their specifications, or both. **Unregistered/ unlicensed medical products** that have not undergone evaluation and/or approval by the national or regional regulatory authority for the market in which they are marketed/distributed or used, subject to permitted conditions under national or regional regulation and legislation. **Falsified medical products** that deliberately/fraudulently misrepresent their identity, composition or source"[16]



Source from WHO

[12] http://www.who.int/medicines/services/counterfeit/impact/ImpactF_S/en/.
[13] Albert I. Wertheimer and Perry G. Wang, Counterfeit Medicines Volume I: Policy Economics and Countermeasures, ILM Publication, 2012, p.5.
[14] *Ibid*, p.6.
[15] WHO, The WHO Member State Mechanism on Substandard and Falsified Medical Products, 2019: https://www.who.int/publications/i/item/WHO-MVP-EMP-SAV-2019.04
[16] WHO, Global Surveillance and Monitoring System for Substandard and Falsified Medical Products, WHO 2017, p. 3.

Table- 2 Definitions of Counterfeit Medicine under National Laws

Country	Definition
China	A drug is a **counterfeit drug** in any of the following cases: 1. the ingredients in the drug are different from those specified by the national drug standards; or 2. a non-drug substance is simulated as a drug or one drug is simulated as another. A drug shall be treated as a **counterfeit drug** in any of the following cases: 1. its use is prohibited by the regulations of the drug regulatory department under the State Council; 2. it is produced or imported without approval, or marketed without being tested, as required by this Law; 3. it is deteriorated; 4. it is contaminated; 5. it is produced by using drug substances without approval number as required by this Law; or 6. the indications or functions indicated are beyond the specified scope.
India	**spurious drugs** are: (a) manufactured under a name which belongs to another drug; or (b) an intimation of, or a substitute for, another drug or resembles another drug in a manner likely to deceive or bear upon it or upon its label or container the name of another drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack identity with such other drug; or (c) labeled or in a container bearing the name of an individual or company purporting to be the manufacturer of the drug, which individual or company is fictitious or does not exist; or (d) substituted wholly or in part by another drug or substance; or (e) purporting to be the product of a manufacturer of whom it is not truly a product
Myanmar	**fake drug** is as follows: (i) a drug the whole or part of the label of which is an imitation or resemblance by various means or is written similarly; (ii) a drug in respect of which the expiration date or manufacturer or distributor or place of manufacture or country of manufacture is fraudulently shown; (iii) a drug in respect of which it is fraudulently shown that it is manufactured according to the formula mentioned at the time of registration of the drug
Philippines	**Counterfeit drug/medicine** refers to medicinal products with the correct ingredients but not in the amounts as provided hereunder, wrong ingredients, without active ingredients, with insufficient quantity of active ingredient, which results in the reduction of the drug's safety, efficacy, quality, strength or purity. It is a drug which is deliberately and fraudulently mislabeled with respect to identity and/or source or with fake packaging and can apply to both branded and generic products. It shall also refer to: (1) the drug itself, or the container or labeling thereof or any part of such drug, container, or labeling bearing without authorization the trademark, trade name, or other identification mark or imprint or any likeness to that which is owned or registered in the Bureau of Patent, trademark, and Technology transfer in the name of another natural or juridical person; (2) a drug product refilled in containers by unauthorized persons if the legitimate labels or marks are used; (3) an unregistered imported drug product, except drugs brought in the country for personal use

Country	Definition
	as confirmed and justified by accompanying medical records, and (4) a drug which contains no amount of or a different active ingredient, or less than 80% of the active ingredient it purports to possess, as distinguished from an adulterated drug including reduction or loss of efficacy due to expiration
Thailand	The following drugs or substances are **fake drugs**: (1) a drug or substance which is wholly or partly an imitation of a genuine drug; (2) a drug which shows the name of another drug, or an expiry date which is false; (3) a drug which shows a name or mark of a producer, or the location of the producer of the drug, which is false; (4) drugs which falsely show that they are in accordance with a formula which has been registered; (5) drugs produced with active substances which quantity or strength lower than the minimum or higher than the maximum standards prescribed in the registered formula under Section 79 by more than twenty percent.

While counterfeiting of branded and generic medicine is increasing in volume and range, it is hard to quantify the actual extent and damage caused by counterfeit drug due to various definitions of counterfeit medicine and the level and frequency of monitoring. There is no universal definition of counterfeit medicine, and many definitions from different countries vary from country to country depending on the various types of counterfeiting which were mostly found in their countries. To safeguard the public health, legal definition of counterfeit medicine should cover potential activities of drug counterfeiting by considering that public interest for health is more important than the private interest or intellectual property rights.

Law Enforcement Activities

The counterfeiting of medicine not only stifles the creation and development of original products but also threatens public health. Law enforcement is one of the keys in combating this problem. In *Principles and Elements for National Legislation against Counterfeit Medical Products* adopted by the WHO's International Medical Products Anti- Counterfeiting Taskforce (IMPACT) in 2007 it suggested that the authorities concerned should establish a legal regime comprising adequate civil and criminal remedies and penalties to deter counterfeiting activities.[17]

Although counterfeiting of medication can be taken by civil and criminal action, most counterfeiters concealed their real place and it is difficult to trace the source to be enforced. In the fight against counterfeit drug it is important to understand that the nature of the fraudulent acts and it is not merely related to intellectual property rights infringement. Drug counterfeiting is related to quality which is important to human health.

The basic framework to combat pharmaceutical counterfeiting is legislation that can establish efficient drug regulation. However, a few WHO member states have enacted specific national laws tackling the issue of counterfeit medicine.[18] "Strict anti-counterfeiting laws cannot by themselves provide protection against fake drugs. In order to be effective, the law must be enforced rigorously and consistently."[19] Usually, law enforcement personnel in doing

[17] The Handbook: International Medical Products Anti- Counterfeiting Taskforce, Facts/Activities/ Documents developed by the Assembly and Working Groups (2006-2010), AIFA, 2011, p. 54.
[18] Albert I. Wertheimer and Perry G. Wang, Counterfeit Medicines Volume I: Policy Economics and Countermeasures, ILM Publication, 2012, p.39.
[19] Mark Davison, Pharmaceutical Anti-Counterfeiting; Combating the Real Danger from Fake Drug, John Wiley & Son, 2011, p.69.

their work effectively are hindered by inadequate tools and training and insufficient manpower to cover the necessary ground.[20] "The efficiency of personnel is adversely affected by the corruption and conflicts of interest, resulting in laws not being enforced and criminals not being arrested, prosecuted and convicted for their crimes."[21]

Case Study and Sanctions

A study in the Philippines revealed that 8% of medicines purchased at drug retailers were fakes, ranging from anti-inflammatory drugs to drugs that purportedly helped with cardiovascular problems and infectious diseases.[22] In Cambodia, Laos, Thailand, Vietnam, and Myanmar, the lack of an active ingredient has been found in more than one-third of the anti-malarial compounds sold.[23] A 1987 Nigerian study found that an astounding 70% of drugs in that country were fake.[24] An estimated 192,000 patients were killed in China from fake drug use in 2001 alone. These deaths occurred in China and the authorities investigated 480,000 incidents of counterfeit drug. Consequently, Chinese authorities closed approximately 1,300 factories.[25]

The WHO estimated that 1 in 10 medical products in low- and middle-income countries are substandard or falsified.[26] INTERPOL reports estimate that falsified medical products could account for as much as 30% of the market in some countries in Asia, Africa and Latin America and more than 20% in economies of the former Soviet Union.[27] It is obvious that counterfeiting of medication is a growing deadly business.

In 2009, Nigeria has seized a large consignment of fake anti-malarial drugs with the label of 'made in India' but found that the medicines were in fact produced in China and were imported into the African countries.[28] This problem is related falsification. Most criminal sanctions for IP infringement are not enough to deter the offenders. They should be punished with imprisonment as a deterrent. As counterfeiters do not operate from a normal business address, they are not detectable to be prosecuted. It is one of the difficulties in enforcement action. Moreover, sanctions imposed on counterfeiters are in most cases not deterrent. The absence of deterrent legislation encourages counterfeiters since there is no fear of being apprehended and prosecuted.

In China, the sentence for offences related fake medicine is up to life imprisonment or death if serious.[29] Under Section 6 of the Drugs and Cosmetics (Amendment) Act of India, 2008, the penalties for spurious drug offences may extend to imprisonment for life. According to the provision regarding offence against fake drug in Section 18 of the 1992 Myanmar National Drug Law, imprisonment for a term may extend to 7 years. The Philippine law relating to counterfeit medicine specifies the offences and sentences in detail and severe penalties such as life imprisonment for drug offenders.[30] In the UK, Medicines and Healthcare Products Regulatory (MHRA) is planning to make dealing in counterfeit medicine a specific

[20] *Ibid.*
[21] Albert I. Wertheimer and Perry G. Wang, Counterfeit Medicines Volume I: Policy Economics and Countermeasures, ILM Publication, 2012, p. 40.
[22] Trish Saywell & Joanne McManus, What's in that Pill?, 2002, p.36.
[23] Merri C. Moken, Fake Pharmaceuticals, 2003, p.528.
[24] Douglas W. Stearn, Deterring the Importation of Counterfeit Pharmaceutical Products, p. 540.
[25] http://medicine.plosjournals.org/archive/1549-1676/2/4/pdf/10.1371_journal.pmed.0020100-S.pdf.
[26] https://www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products
[27] https://www.oecd-ilibrary.org/sites/fe58fe07-en/index.html?itemId=/content/component/fe58fe07-en#figure-d1e2108
[28] http://www.who.int/medicines/services/counterfeit/impact/ImpactF_S/en/.
[29] Article141 of the Criminal Law of China, 1979
[30] Section 8 of the Philippine Special Law on Counterfeit Drugs, 1996.

criminal offence, with the most serious offences carrying terms of imprisonment of up to 12 years.[31] Penalties relating to counterfeiting vary from country to country and criminal sanctions also vary according to the characteristics of the offences. The provision concerning punishment which prescribes either imprisonment or fine can create a loophole for offenders and criminal sanction imposed on drug counterfeiters should be severe penalties with imprisonment.

Regional Effort to fight against Counterfeit Medicine

Counterfeit medicine are a global threat that requires global, regional and national solutions. All ASEAN member countries are net importers of pharmaceutical. This means that these countries import most raw materials to produce finished drug preparations locally. All countries also finished products to fill domestic demand. In addition, some member countries manufacture finished drug products for exports as well. Registration system is one of the transparent ways so as to improve access and use of medicines. Efforts by the Association of Southeast Asian Nations (ASEAN) to create a harmonized medicines regulatory process are regional initiative on medicines regulation.[32]

As the global supply drugs are huge and growing, it is obvious that the drug market would be a main target for counterfeiters. All counterfeit drugs are absolutely illegal, whether they are dangerous or not. Drug regulation is totality of all measures which include legal, administrative and technical. Governments take to ensure quality, efficacy and safety of drugs through these measures. Each of the ASEAN member countries has regulatory system in pharmaceutical sector.

ASEAN requires regional anti-counterfeiting measure to control the counterfeit drug, despite the registration harmonization system. In ASEAN countries the national drug registration system is not functioning satisfactorily, with some marketed drugs with no valid registration, labeled with incorrect registration numbers, or registered but non-compliant with specifications.

The European Union took an important step forward on a regional basis when the European Parliament approved an amendment to the European Community's existing directive respecting trade in pharmaceutical products to deal with internet sales and impose new safety and traceability requirements. The evolution of the concept of pharmaceutical crime or 'medicrime' is an attempt by the council of Europe to address this shortcoming by framing clear and specific offences in law, in the so-called Medicrime Convention.[33]

The 'Medicrime Convention' is the first international criminal law instrument imposing obligation on "States Parties to criminalise:

- the manufacturing of counterfeit medical products;
- supplying, offering to supply and trafficking in counterfeit medical products;
- the falsification of documents;
- the unauthorised manufacturing or supplying of medicinal products and the placing on the market of medical devices which do not comply with conformity requirements."[34]

The Convention provides a framework for national and international co-operation across the different sectors. Furthermore, at EU regional level Directive 2011/62/EU relating to

[31] http://www.pharmatimes.com/news/uk_mhra_plans_up_to_12_years_jail_for_counterfeit_dealing_ 982863
[32] WHO, WIPO and WTO, Promoting Access to Medical Technologies and Innovation, 2013, p.50.
[33] www.coe.int/t/dghl/standardsetting/medicrime/CDPC%20_2009_15Fin%20E%20draft% 20 Convention%2009%2011%2009CM.pdf.
[34] https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/211

falsified medicinal products is one of the most important tools as it sets out the rules to tackle the alarming increase in the number of falsified medicinal products.

In the Guiding Principles from the report of the fifth meeting of the Member State mechanism on substandard/spurious/falsely labeled/ falsified/counterfeit medical products by WHO's Assembly "a national or regional plan would lead to the development of legislative instruments, and legislation enforcement would contribute to the desired outcomes. National or regional legislations on SSFFC medical products should include effective and appropriate enforcement tools and penalties, as well as adequate resources."[35]

In regional networking on combating counterfeit drug, member States should clarify the term of "counterfeit" that covers potential activities of drug counterfeiting in national drug legislation in order to facilitate the lack of coordinated anti-counterfeiting initiatives by various national regulatory agencies.

Global Cooperation to Combat Counterfeit Medicine

In combating counterfeit drugs, the cooperation between the pharmaceutical industry, wholesalers, and retailers is necessary to inform the national drug regulatory authority about suspect drugs. The cooperation between regulatory authorities, police, and customs services and the judiciary is essential for effective control of the national drug market and enforcement of drug legislation. When such cooperation is ineffective, counterfeiters can escape detection, arrest, and penal sanctions. In 1998, the serious public health problem in South East Asia of counterfeit artesunate evidence is obtained that some of the counterfeit artesunate was manufactured in China. International cross-disciplinary collaborations may be appropriate in the investigation of other serious counterfeit medicine public health problems elsewhere, and strengthening of international collaborations and forensic and drug regulatory authority capacity will be required within national, regional and international level.

IMPACT was launched to control counterfeit drug problem in 2006 comprising organizations such as the WHO, International Criminal Police Organization (INTERPOL), OECD, World Customs Organization (WCO), World Intellectual Property Organization (WIPO), World Trade Organization (WTO), International Federation of Pharmaceutical Manufacturers Association (IFPMA), World Bank, European Commission, Council of Europe, International Pharmaceutical Federation, Pharmaceutical Security Institute. [36] However, IMPACT was removed from WHO, and governments fought over terms (including falsified) until they settled on a contortion that in a way perfectly reflected the level of disagreement among them: substandard/ spurious/ falsely-labelled/ falsified/ counterfeit medical products, or SSFF.[37]

"In cases of falsified medical product-related crime among the possible issues are the admissibility of evidence obtained from foreign law enforcement agencies through mutual legal assistance and international cooperation and the transmission of evidence to forensic services located in foreign jurisdictions." [38] At the international level, the operations by INTERPOL are encouraging closer collaboration between the health sector, law enforcement authorities, international organizations and non- governmental organizations around the

[35] https://apps.who.int/gb/ebwha/pdf_files/EB140/B140_23-en.pdf
[36] http://www.who.int/medicines/services/counterfeit/IMPACTOrgParts.pdf.
[37] http://www.ip-watch.org/2011/03/03/who-working-group-gives-guidelines-to-fight-bad-medicines-impact-in-exile/
[38] UNODC, Combating Falsified Medical Product-related Crime: A Guide to Good Legislative Practices, United Nations, Vienna, 2019, p.62.

globe.[39] As most illicit trade of counterfeit medicine is a trans-border crime, cooperation between regulatory authorities and stakeholders needs to be strengthened in tackling at national and international level.

Findings

Counterfeit medicine is a serious danger to health, especially during pandemic situation. The number of counterfeits is increasing with the growth of illegal online pharmacy. There is no globally accepted legal instrument concerning anti-counterfeiting of medication and a lack of precise definition covering counterfeiting activities. In order to eliminate counterfeit medicine, closer and stronger trans-border cooperation is the need for constant vigilance at both regional and international level.

Conclusion

In order to be a global standard for anti-counterfeiting action, a corresponding and sufficiently precise definition is in need. Sale of drugs through the internet leads to increase circulation of counterfeit medicines in national and international markets. Strict regulations on the online pharmacy including traditional drug sales should therefore be established. As Myanmar is also facing the challenges of counterfeiting problems, public awareness of the counterfeit medicine and its effects need to be promoted. To create a safe pharmaceutical market for better public health, raising public awareness, an effective enforcement system and using advanced technologies are essential.

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