



Chapter Nine

GLOBAL THREAT OF COUNTERFEIT MEDICINES

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INTRODUCTION

Drug is a substance used to modify physiological or pathological states for the benefit of the recipient. It is the single chemical substance that forms the active ingredient of medicine, active pharmaceutical ingredient (API) that produces a pharmacological activity. Also, drug is any substance or mixture of substances manufactured, sold or advertised for use by man or animal for the purposes of diagnosis, treatment, mitigation or prevention of any disease or disorder abnormal physical state or symptoms thereof Restoration, correction or modification of organic functions, disinfection, the control of vermin, insects, pests or contraception (Pharmacists Council of Nigeria [PCN], 2009a).

The term “medicines” is used instead of “drugs” to describe pharmaceutical preparations used in clinical health care practice (World Health Organization [WHO], 2002). Also, the non-native English speakers frequently associate the word “drugs” with narcotic or illicit substances (hard drugs).

OBJECTIVES

At the end of this chapter, the students are expected to:

- (i) give a definition drug;
- (ii) understand a global perspective of counterfeit medicines;
- (iii) describe the magnitude of the burden of counterfeit medicines;
- (iv) list factors that encourage counterfeiting of medicines;
- (v) discuss the implications of counterfeit medicines; and
- (vi) list and explain anti-counterfeit measures in the Pharmaceutical industries

According to World Health Organization (WHO, 2003a), a counterfeit medicine (CM) is one which is deliberately and fraudulently mislabeled with respect to identity and/or source (WHO, 2003a). The term counterfeiting can apply to both branded and generic products. CM may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or fake packaging. CM involves a deliberate or intentional attempt to deceive (WHO, 2003a).

However WHO Member States have slight variations of the definition of counterfeit medicines. For instance,

1. United States (U.S.) Federal Food, Drug & Cosmetics Act defines CM as a drug which, or the containers or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drugs, thereby, falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor (WHO, 2003a).

2. Pakistan Manual of Drug Laws defines CM as a drug, the label or outer packing of which is an imitation of, resembles or so resembles as to be calculated to deceive, the label or outer packing of a drug manufacture (WHO, 2003a).
3. Philippines Republic Act No. 82036 defines CM as medicinal products with correct ingredients but not in the amounts as provided, wrong ingredients, without active ingredients, with insufficient quantity of active ingredients, which results in the reduction of the drug's safety, efficacy, quality, strength or purity. The CM is deliberately and fraudulently mislabeled with respect to identity and/or source or with fake packaging, and is can applicable to both branded and generic products (WHO, 2003a).
4. Nigerian Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous Provisions) Decree, defined fake drug as "any drug product which is not what it purports to be; or any drug or drug product which is so colored, coated, powdered or polished that the damage is concealed or which is made to appear to be better or of greater therapeutic value than it really is, which is not labeled in the prescribed manner or which label or container or anything accompanying the drug bears any statement, design, or device which makes a false claim for the drug or which is false or misleading; or any drug or drug product whose container is so made, formed or filled as to be misleading; or any drug product whose label does not bear adequate directions for use and such adequate warning against use in those pathological conditions or by children where its use may be dangerous to health or against unsafe dosage or methods or duration of use; or any drug product which is not registered by NAFDAC in accordance with the provisions of the Food, Drugs and Related Products (Registration, etc.) Decree 1993, as amended (WHO, 2003a)."

Moreover, International Pharmaceutical Federation (FIP) in collaboration with Commonwealth Pharmaceutical Association (CPA) defined CM as medicinal products which have been deliberately and fraudulently mislabeled with respect to identity and/or source (International Pharmaceutical Federation [FIP], 2011).

Thus, CMs include products with correct ingredients, wrong ingredients, no active pharmaceutical ingredient (API) or fake labeling, substandard product with correct labeling. Other terminologies such as Substandard Medicines and Adulterated Medicines also come under counterfeiting of medicines.

Substandard Medicines (SMs) are genuine medicines also referred to as out-of-standard (OOS) products (WHO, 2006a), but they do not meet quality specifications set for them (WHO, 2006a, WHO, 2003a). SMs is a term used to describe the quality status of genuine medicines. Legitimate manufacturers adhere to official specifications laid down by official Pharmacopoeias: British Pharmacopoeia (BP), United States Pharmacopoeia (USP), and European Pharmacopoeia (EP) for the production of their products. Thus, SMs fail to meet the pharmacopoeia specifications used for its formulation with regards composition and ingredients

Adulterated Medicines (AMs) are medicines in which the methods used in, or the facilities or controls used for its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current Good Manufacturing Practice (cGMP) to assure that such medicines meet the requirements of the Food and Drugs Act as to the safety (United States Code [U.S.C.], 2010). Such medicines do not have the identity, strength, quality and purity characteristics which they

purport to be or are represented to possess (Swaminath, 2008). AMs purport to be or are represented as medicines whose names are recognized in an official compendium, but have strength differing from the standard set forth in such compendium. In addition, they have quality or purity that fall below the standard set forth in such compendium. AMs consist in whole or in part any filthy, putrid or decomposed substance, or any medicine that has been prepared, packaged or stored under unsanitary conditions where it may have been contaminated with filth thereby rendering it injurious to health. An AM is also any medicine that is packed in a container which is composed in whole or in part of any injurious or deleterious substance which may render the content injurious to health. Any medicine which bears or contains for the purposes of colouring, any colour other than one which is prescribed, or contains any harmful or toxic substance which may render it injurious to health, or has been mixed with some other substance so as to reduce its quality or strength is also AM (Swaminath, 2008).

Thus, CMs include products with correct ingredients, wrong ingredients, no active pharmaceutical ingredient (API) or fake packaging and labeling, substandard and adulterated products with correct labeling. These can be illustrated “mathematically” as shown below:

- ❖ Fake packing and/or labeling + correct quantity of correct ingredient = counterfeit medicine.
- ❖ Fake packing and/or labeling + incorrect quantity of correct ingredient = counterfeit medicine.
- ❖ Fake packing and/or labeling + no active ingredient = counterfeit medicine.
- ❖ Fake packing and/or labeling + wrong ingredient = counterfeit medicine.
- ❖ Genuine packing and/or labeling + incorrect quantity of correct ingredient (deliberate) = counterfeit medicine.
- ❖ Genuine packing and/or labeling + no active ingredient (deliberate) = counterfeit medicine.
- ❖ Genuine packing and/or labeling + wrong ingredient (deliberate) = counterfeit medicine.
- ❖ Genuine packing and/or labeling + incorrect quantity of correct ingredient (not deliberate) = substandard medicine.
- ❖ Genuine packing and/or labeling + unsanitary processing (Bad Manufacturing Practice) = adulterated medicine.
- ❖ Genuine packing and/or labeling + unsanitary facility for processing (Bad Manufacturing Practice) = adulterated medicine.
- ❖ Unsanitary packing and/or labeling + unsanitary facility and processing (Bad Manufacturing Practice) = adulterated medicine.
- ❖ Genuine packing and/or labeling + correct quantity of correct ingredient + sanitary facility and processing (cGMP) = genuine medicine.

MAGNITUDE OF THE BURDEN

Menace of counterfeit medicines is recognized internationally. It exists in developed and developing countries. However, the true extent of the problem is not known due to lack of global studies. Appearance of CMs in International commerce was first mentioned as problem at WHO Conference of Experts on rational Drug Use in Nairobi, Kenya 1985 (WHO, 2003a). It has assumed greater importance due to

globalization. Globally, it is one of the fastest growing grey economies after prostitution, narcotics, terrorism and arm trade (Swaminath, 2008). According to WHO estimates, CMs are up to 10% of pharmaceutical trade of which 25% is consumed in developing countries. Also, the US based Centre for Medicines in the Public Interest predicted that, counterfeit drug sales will reach US\$ 75 billion globally in 2010, which is a 90% increase from 2005 (WHO, 2006b).

Reports of 771 cases of substandard medicines were entered into the WHO database on counterfeits in April 1999, of which, 77% were from developing countries. Analysis of the data showed that 60% of the 325 cases had no active ingredient in the product (WHO, 2003b). Another study in *The Lancet* concluded that up to 40% of artesunate products (anti-malarial medicines) contain no active ingredients which result in no therapeutic benefits (WHO, 2003b). Also, GlaxoSmithKline in the United States discovered counterfeiting of medicines used for HIV/AIDS treatment in 2002 in which bottles containing Ziagen® (abacavir sulphate) were mislabeled Combivir® (WHO, 2003b). Since both medicines are part of combination therapies for HIV/AIDS, there is potential life threatening adverse drug reactions and toxicity.

There were 46 confidential reports relating to counterfeit medicines from 20 countries that were received by WHO between January 1990-Oct 2000 of which about 60% are from developing countries while 40% from industrialized countries (WHO, 2003b). However, Chakravarty et al (as cited in Gautam et al, 2009) stated that vast majority of CMs are thought to be produced in China, India and Russia, though significant numbers of illegal factories have been reported in Nigeria and Philippines. Fake medicines are estimated to represent 13-30% of pharmaceutical market in India and about 75% cases of CMs originate from India being a major exporter of CMs to developing countries including ARVs (Chakravarty et al as cited in Gautam et al, 2009).

In 2006, Peru's counterfeit drug sales have risen from an estimate of US\$ 40 million in 2002 to US\$ 66 million while Russia's Federal Service for Health Sphere Supervision reported that 10% of all drugs on the Russian market were counterfeit (WHO, 2006b). According to WHO report of CMs for 2005, 50% of the pharmacies in Dominican Republic operated illegally while 10% of the medicines that arrived in the country were fake and the commercialization of counterfeit medicines generated economic losses of around \$40 million to the pharmaceutical industry of El Salvador. In addition, counterfeit pharmaceutical products account for approximately \$130 million annual sales in Kenya while pirated drugs constituted 25% of Indonesia's \$2 billion pharmaceutical market (WHO, 2006b). The WHO reports of CMs for 2004 shows that approximately 70% of medicines used by the Angolan population were forgeries; an estimate of US\$60 million or 5% of the total annual market of medicines sold in Colombia were contraband, counterfeit or adulterated; 35% of pharmaceuticals available in the Lebanese market were counterfeit while illegal products represented about 10% of the pharmaceutical market in Mexico (WHO, 2006b). WHO reports of CMs for 2003 showed that 30% of drug store outlets visited by food and drug deregulation officers carry and sell counterfeit drugs. Also, WHO reports of CMs for 2002 revealed that 13% of the drugs on Cambodia domestic market were counterfeit or substandard; an estimation of about 8% of over-the-counter drugs sold in China are counterfeit; an estimated illegal drugs growth in India was estimated to be from 10% to 20% of the total

market while the countries' pharmaceutical companies claimed a loss in revenue of between 4% and 5% annually.

In Nigeria, the era 1985 to 2000 heralded the regime of counterfeiting of products medicines inclusive (Akinyandenu, 2013; Erhun et al, 2001). Furthermore, an estimate of 70% of drugs in circulation in Nigeria was either fake or adulterated in 2002 while 48% of goods and drugs imported into the country in 2004 were substandard or counterfeit (WHO, 2006b).

Internet-based sales of pharmaceuticals are a major source of counterfeit medicines (WHO, 2006b). Pre-requisite for legally operated Internet pharmacies include government licensed facilities and dispensing of medication on presentation of a valid patient prescription. However, WHO reports showed that illegal Internet pharmacies are operated internationally, sell products that have an unknown or vague origin and sell medications without prescriptions (WHO, 2006b).

The death casualties due to CMs are enormous. In Nigeria, 109 children died after the use of paracetamol syrup in 1990 (Bonati, 2009) while 14 children died after the administration of chloroquine phosphate injection in 1994 (Aluko, 1994). Also, Nigerian supply of 88,000 Pasteur Merieux and SmithKline Beecham meningitis vaccines to Niger in 1995 resulted in about 2,500 deaths after vaccination (Akinandenu, 2013) while 84 children were reported dead between late 2008 and early 2009 due to diethylene glycol-contaminated My Pikin Baby Teething Mixture (Bate et al, 2009). Also, there were cases of counterfeit artesunate-amodiaquine (Ehianeta et al, 2012). The battle against counterfeit medicines in Nigeria led to the promulgation of the Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous Provisions) Act No.25 of 1999 which makes provision for the prohibition of sale and distribution of counterfeit, adulterated, banned, fake, substandard or expired drugs (PCN, 2009b). In addition, the promulgation of National Agency for Food and Drug Administration and Control (NAFDAC) Decree No. 15 of 1993 led to the establishment of NAFDAC with the mandate: to regulate and control quality standards for foods, drugs, cosmetics, Medical devices, chemicals, detergents and packed water imported, manufactured locally and distributed in Nigeria. The Federal task force on Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous Provisions) Act operates within NAFDAC

Other CMs casualties include 89 people died in Haiti after using cough syrup containing di-ethylene glycol 1995 (WHO 2006b) and 30 people died in Cambodia after taking counterfeit antimalarial medicine in 1999 (WHO 2006b). Furthermore, 38% of 104 antimalarial drugs for sale in pharmacies in Southeast Asia did not contain any active ingredients, causing a number of preventable deaths from the disease according to a study in 2001 (WHO 2006b). In 2004, a trail of death was caused by fake medicine (WHO, 2006b).

All kinds of medicines have been counterfeited which include antibiotics, hormones, analgesics, steroids, and antihistamines. These drugs form almost 60% of the products reported. In terms of types of counterfeits and their magnitude, the products reported can be grouped into six categories (WHO 2003a):

- Products without active ingredients, 32.1%;
- Products with incorrect quantities of active ingredients, 20.2%;
- Products with wrong ingredients, 21.4%,

- Products with correct quantities of active ingredients but with fake packaging, 15.6%;
- Copies of an original product, 1%; and
- Products with high levels of impurities and contaminants, 8.5%.

Specific examples of counterfeiting showing country of origin, the year and the type of counterfeiting are as shown in the table below (WHO 2012):

SFFC medicine	Country/Year	Report
1. Avastin (for cancer treatment)	United States of America, 2012	Affected 19 medical practices in the USA. The drug lacked active ingredient
2. Viagra and Cialis (for erectile dysfunction)	United Kingdom, 2012	Smuggled into the UK. Contained undeclared active ingredients with possible serious health risks to the consumer
3. Truvada and Viread (for HIV/AIDS)	United Kingdom, 2011	Seized before reaching patients. Diverted authentic product in falsified packaging
4. Zidolam-N (for HIV/AIDS)	Kenya, 2011	Nearly 3 000 patients affected by falsified batch of their antiretroviral therapy
5. Alli (weight-loss medicines)	United States of America, 2010	Smuggled into the USA. Contained undeclared active ingredients with possible serious health risks to the consumer
6. Anti-diabetic traditional medicine (used to lower blood sugar)	China, 2009	Contained six times the normal dose of glibenclamide. Two people died, nine people were hospitalized
7. Metakelfin (antimalarial)	United Republic of Tanzania, 2009	Discovered in 40 pharmacies. The drug lacked sufficient active ingredient

FACTORS ENCOURAGING COUNTERFEITING OF MEDICINES

1. Lack of or weak enforcement of existing laws on the quality, safety and efficacy of both imported and locally manufactured medicines encourage counterfeiting. Offenders are not afraid of arrest and prosecution (WHO, 2003a)
2. Weak penal actions encourage medicine counterfeiting since there is no fear of being apprehended and prosecuted. This is especially so when there are more severe penalties for counterfeiting non-medicinal products (WHO, 2003a).
3. Absence of or weak drug regulation encourages counterfeiting of medicines. The unique role of medicines require that they be safe, effective and of good quality in order to produce the desired therapeutic effect. To ensure these properties, it is necessary to create a competent national drug regulatory authority with the necessary human and other resources so that the manufacture, importation, distribution and sale of medicines can be adequately regulated (WHO, 2003a).
4. Corruption and conflict of interest adversely affect enforcement of laws prohibiting counterfeiting of medicines (WHO, 2003a).
5. High remunerative trade also encourages counterfeiting of medicine. Low cost of manufacture of counterfeit medicines coupled with high demand for medicines result in significantly high profits (WHO, 2006b).
6. Lack of cooperation between stakeholders results in counterfeiters escaping detection, arrest, prosecution, and conviction. Also, failure of pharmaceutical manufacturers,

wholesalers, retailers and the public to report to national drug regulatory authorities contribute to the flourishing of the menace (WHO, 2003a).

7. Lack of control by exporting countries and within free trade zones results in flourishing of counterfeit medicines. Many exporting countries do not regulate export pharmaceutical products to the same standard as those for domestic use. Pharmaceutical products are sometimes exported through free trade zones where drug regulation is lax, giving room for repackaging and relabeling (WHO 2012).
8. Availability/accessibility of advanced technology encourage counterfeiting. A study in The Lancet showed that counterfeiters' ability to reproduce holograms and other sophisticated printing techniques had dramatically improved between 2001 and 2005, making detection even more difficult (WHO 2006b).
9. Poverty sustains counterfeiting. Paying for medicines constitute major recurrent public health expenditures (second to salaries) and also account for over half of all private health expenditures (Dukes, 1997). Some people seek medicines that are sold more cheaply. These are often available from non-regulated outlets, where the incidence of counterfeit medicines is likely to be higher.
10. Low-availability of testing facilities makes detection of counterfeit medicines difficult. Thus, offenders are emboldened to perpetuate counterfeiting.

IMPLICATIONS OF COUNTERFEIT MEDICINES

1. Public Health Crisis

Counterfeit medicines pose a serious public health threat. This is because their content could be dangerous due to contamination, inadequate or no active ingredient resulting in treatment failure. Ineffective treatment can lead to a complex series of woes (WHO, 2012) such as:

- drug resistance
- obsolescence of cheap effective drugs as in the case of anti-malarial medicines
- adverse drug reactions
- increased morbidity (illness)
- mortality (death),
- decline in confidence in public health care systems and healthcare professionals
- Loss of confidence of health care practitioners in the medications.

There are also cases of toxicity associated with counterfeit medicines which also leads to the complex series of woes as above.

The complexity of the health crisis due to counterfeit medicines can be best imagined and appreciated with a consideration of the following counterfeit medicine case:

“After his first in-center dialysis in January 2008, Randy Hubley of Toledo, Ohio suffered severe abdominal pain, diarrhea, and shortness of breath. Two days later, Randy collapsed and did not regain consciousness. Investigations attributed his death to heparin, an anticoagulant that treats blood clotting during kidney dialysis. According to reports, the heparin used before his treatment was counterfeit—the drug was contaminated with oversulfated chondroitin sulfate, a compound that is structurally similar to heparin, rendering detection of the false substance extremely difficult. Counterfeit heparin induces severe allergic reactions; in 2008, the FDA documented 81 deaths and about 600 allergic reactions linked to the tainted drug. Its origin was traced back to a production plant in

Changzhou, China, which also exports pharmaceuticals to Germany, Canada, France, Italy, and other countries” (Finlay, 2011).

2. Threat to National and International Security

According to Finlay (2011), counterfeiting of medicines poses a threat to national and international security. The profits accrued from this sinister crime are increasingly being co-opted by an array of organized criminal and terrorist entities to fund their despicable operations globally (Finlay, 2011).

3. Negative Economic Impact

Poor therapeutic outcomes also have economic implications. Huge finances are wasted as result of microbial resistance, increased morbidity, hospital admission and long hospital stay, poor quality life, loss of income/low productivity. The economic impact on part of the consumer can be summarized by the slogan “Health is Wealth”. Huge wastage of resources (money, man, minutes, material and information) of pharmaceutical manufacturers, wholesalers and retailers due to product obsolescence (as a result of microbial resistance) and product expiration (due to low/no product turnover) (West, 2009). Nationally, there is loss of revenue since counterfeiters evade legitimate taxation (Finlay 2011).

4. Intellectual Property Rights

Counterfeiting of medicines also violates Intellectual Property (IP) Rights as a result of unlawfully bearing a registered trademark in which case the victims of counterfeiting are the trademark owners (Burci, 2013). The breach of IP may include patency and industrial design.

ANTI-COUNTERFEIT MEASURES IN PHARMACEUTICAL INDUSTRY

The common and familiar anti-counterfeit measures currently in use in Nigeria include:

1. Tamper-evident/tamper-resistant packing,

The product packing has an indicator or entry barrier which provides visible or audible evidence to the consumers that the product has been tampered with, if breached or missing. Examples include blister packs, tape seals, shrinkable seals, film wrappers and breakable caps (Bansal et al, 2013).

2. Holograms: There could be combination of three layered security features (Bansal et al, 2013):

- a. Overt features,
- b. Covert features such as micro-text, scrambled images UV-sensitive or specialized.
- c. This requires trained examiners and appropriate decoding equipment.
- d. Serialization of hologram. Authentication is combined with traceability.

3. mPedigree: This is a type of track and trace system. An offshore data centre tracks the codes which are randomly generated by the pharmaceutical manufacturer. The medicine pack has a distinctive panel that reveals a ten-digit code when scratched. This code is sent to a central number through a short message service (SMS) and a response to the SMS is received. The response indicates whether the medicine is genuine or counterfeit (Sharma, 2011).

In Nigeria, mPedigree has been incorporated into the national quality assurance standards for pharmaceuticals by the Nigeria Government (Sharma, 2011). The practical steps involved in the use of mPedigree in Nigeria are:

- a. Scratch the distinctive panel (card) to reveal the **PIN**
 - b. Text **PIN** to **38353**.
 - c. Wait for a response.
- Note:** Text **PIN** only **ONCE**.

AUTHENTICATION OF A PHARMACEUTICAL PRODUCT USING ANALYTICAL METHODS

Analytical methods such as chromatography (High Performance Liquid Chromatography (HPLC), Gas Chromatography (GC) coupled with optical, electrochemical or mass detectors, Thin-Layer Chromatography (TLC), Colorimetry, optical spectroscopy, and isotopic characterization, Near Infra-Red (NIR) and Raman spectroscopies are used to authenticate pharmaceutical products. Raman spectroscopy is an analytical technique which uses the interaction between light and molecular bonds to characterize individual chemicals such that each compound creates a unique fingerprint.

Currently in Nigeria, TruScan Handheld Raman Spectrometer is used by NAFDAC to detect counterfeit medicines. TruScan identifies the slightest difference in the medicine formulation. The user is alerted with a clear “pass” or “fail” reading within seconds of use.

RECOMMENDATIONS FOR COMBATING COUNTERFEIT MEDICINES

1. There should be development of appropriate medicines policy options, legislation, and enforcement strategies by each country at a national level. The policies should involve all stakeholders.
2. The governments of each country should demonstrate political will/commitment for evolving and implementing programs for combating counterfeit medicines. Political will and commitment should be demonstrated by:
 - a. Enacting new drug laws or updating existing drug laws that prohibit counterfeit medicines.
 - b. Establishing institutions for the regulation of medicines and clearly setting out in the drug laws, the power, duties and responsibilities of the institution(s)
 - c. Training of personnel, including enforcement officers, for national drug control.
 - d. Making available necessary financial and other resources.
 - e. Ensuring that the drug laws are enforced.
 - f. Continuous investment in technologies and strategies that detect counterfeit medicines.
 - g. Fostering international cooperation in the control of pharmaceutical.
 - h. Entering into bilateral and multilateral agreements with other governments and with international organizations such as World Health Organization (WHO), Interpol and the World Customs Organization (WCO).
3. Judicial procedures and policies should reflect the seriousness of the problem and the offence. There should speedy disposal of cases involving counterfeit medicines. Also severe penal sanctions on convicted offenders should be imposed. Confiscation/forfeiture and destruction of counterfeit medicines should be ordered by the courts.

4. Combating counterfeiting of medicines is a shared responsibility of all persons. Non-Governmental Organizations (NGOs) and Community Based Organizations (CBOs) should be provided with information and methods for counterfeit medicines detection, in order to report cases to the national drug regulatory agencies.
5. Education and information campaigns about the menace of counterfeit medicines, legitimate sources of genuine medicines and the need of patients to inform their prescriber about treatment failure and ADRs should be directed at the general public.
6. Demonstration of greater cooperation between countries at sub-regional, regional and international levels so that privatization and liberalization of the world economy and extensive opening of borders to trade do not contribute to proliferation of counterfeit medicines
7. Internet pharmacy practice should also be regulated through licensure
8. International convention to control trade in counterfeit medicines should be organized by WHO Member States.

CONCLUSION

CMs cause serious public health crisis and constitute major threat to National and International Security. They create negative economic impact and violate Intellectual Property Rights. It is a must to take positive actions today to combat CMs. We must not forget: **No action today, no solution tomorrow!**

EVALUATION STRATEGIES

Practice Questions

1. List six (6) examples of reported counterfeiting stating the products; country and year of occurrence; and the type of counterfeiting.
2. Counterfeiting of medicines constitute a global threat. Describe the magnitude of the burden of counterfeiting.
3. Discuss the implications of counterfeiting of medicines as a global threat.
4. Describe the mPedigree in the context of anti-counterfeiting of medicines.
5. What factors have contributed to increased prevalence of counterfeit medicines

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