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Outcomes of Counterfeit Drugs in the Prevention and Treatment of Diseases and Organic Dysfunctions in Africa

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Abstract - I would like thank Prof. Yemane Berhane for his close guidance and technical assistances from inception to the end of this paper. My special thanks also go to my wife, W/ro Helen Bekele and my kids, Herma Addis and Michael Addis for their encouragements and family help to realize and complete my MPH studies.

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OUTCOMES OF COUNTERFEIT DRUGS IN THE PREVENTION AND TREATMENT OF DISEASES AND ORGANIC DYSFUNCTIONS IN AFRICA

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Outcomes of Counterfeit Drugs in the Prevention and Treatment of Diseases and Organic Dysfunctions in Africa

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I. ACKNOWLEDGEMENTS

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II. SUMMARY

The WHO defined counterfeit medicine as one which is deliberately and fraudulently mislabeled with respect to identity and/or source. There are many ways of presenting counterfeit drugs by the black marketers. Branded and generic drugs could be counterfeit and these products may contain the right or wrong ingredients; without active ingredients, with insufficient active ingredients or with fake packaging. The availability of counterfeit drugs in the market is considered by any country as problem. Published articles indicate that in developing countries a wide spectrum of types of counterfeit drugs, ranging from the precise copy of a genuine product to the extreme case of a drug product with none of the correct active ingredient exist.

Counterfeit drugs are a major threat for the treatment of deadly diseases, including malaria, tuberculosis, HIV/AIDS, and other chronic diseases in Africa. Development of drug resistant pathogenic organisms due to counterfeit drugs containing little quantities of the active ingredients has not only cause treatment failure and spread of drug resistant strain of the pathogenic organisms but also contribute to the death and disability of the patients who have taken the drug. Moreover, it incurs huge care and treatment cost while shifting the patient to the newer and costly drugs. This ultimately affects the country's health system and contributes to the loss of confidence on the health professionals who are giving the service to the patients in particular and the country's health system in general.

The widespread distribution of these drugs and troubling victimization rates added up to a long list of health and wellbeing challenges in the region. Apart from their role in compromising the prevention and treatment of diseases and organic dysfunctions, they are known to kill quite a huge number of people in African countries. Likewise, they are also known of depriving the revenue of these countries.

Countries should work in harmony to stop and control the manufacturing and distribution of counterfeit drugs. Above all, African countries should work hard to have a strong drug administration and control regulatory authorities and a strong Pharmacovigilance system which have a legal power to control and stop this rampant problem which is playing with the lives of citizens.

III. BACKGROUND

The World Health Organization (WHO) defines counterfeit medicines as those that are deliberately and fraudulently mislabeled with respect to identity or source: their quality is unpredictable as they may contain the wrong amount of active ingredients, wrong ingredients or no active ingredients(1). They are usually manufactured in illegal and hidden laboratories which range from cottage to large factories that do not have any quality control system(1, 2). Their availability in the developing countries' market occurs in unregulated market and most of the vendors are not official or licensed (2).

Counterfeit drugs are predominantly available in countries where the custom procedure is not stringent and this usually results in loss of public confidence in the health care system. Among other drugs, life saving drugs are the principal target of counterfeiters(2). Moreover, among many methods of counterfeiting drugs, mimicking branded products in terms of their packaging and dosage forms would enable counterfeiter's to pass custom inspection easily. As these products are very similar to the original brands, they can be accepted by distribution and retails companies(3). Some studies showed that the pharmaceutical industry lost USD 30 billion as a result of counterfeit drugs in 2005 alone(4).

Though the overall death due to counterfeit drugs is not well known, it is a fact that its damage on

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the costs of public health is so huge. Among other direct impacts on individuals, resistance to medicine for curing diseases is considered to be the leading cause of mortality as a result of treatment failure. Counterfeit anti malarial drugs are also contributing a lot in the death of a million people around the world(5). The prevalence of counterfeit drugs in developing countries is very high and it is estimated to be 60% in countries which are found in African and Southeast Asia. Apart from this, most of the counterfeit drugs are those that are used to treat serious diseases such as malaria, tuberculosis and HIV/AIDS(6). In general, counterfeit drugs are made in various categories ranging from life-threatening diseases such as diabetes to simple pain killers and other lifestyle products such as drugs for erectile dysfunctions(2).

There are also some countries like India and china which are playing prominent role in the production of counterfeit drugs which is very much associated with the permissive legislation and inefficient judiciary system, absence of qualified supervising staff and widespread corruption(3, 7).

The counterfeit drug issue was first discussed in World Health Assembly in 1989 and launched the International Medical Products Anti-Counterfeiting Task Force (IMPACT) up to 2016 to enforce and tackle the counterfeit drugs problem in the world(5).

a) Objectives

The general and specific objectives are mentioned below:

i. General objective

To assess the health outcomes of counterfeit drugs on the prevention and treatment of diseases and organic dysfunctions.

ii. Specific Objectives

1. To review the health outcomes of counterfeit drugs on diseases and organic dysfunctions with special emphasis on Africa.
2. To indicate the magnitude, sources and distribution of counterfeit drugs in Africa in particular and the world in general.

IV. METHODS

Published articles which are freely available from the PubMed were searched using the following key words and the followings were found: 121 published articles using 'counterfeit drugs' limiting the year below 10 years and in English language; 37 published articles using 'Counterfeit drugs AND Africa' limiting the years below 10 years and in English language; 19 published articles using 'Counterfeit drugs AND sources in Africa' limiting the years below 10 years and in English language; 11 published articles using 'Counterfeit drugs AND determinants in Africa' limiting the years below 10 years and in English language. I also accessed DOAJ

with the same key words; nevertheless, I could not find any published article on the subject.

The abstracts were then down loaded, read and selected 22 published articles which have direct relevance and which also comply with the objectives of the review. Twenty two articles were downloaded and kept them in a folder for review and queries which may be raised either by the readers or my advisor. All of them were read and tried to understand the core messages and findings which are indicated in the articles. To comply with the objectives, the review focused on:

- The sources of counterfeit drugs and the rationale behind why they are available in the market.
- The prevalence, magnitude and distribution of counterfeit drugs in Africa in particular and the world in general.
- The health effects they are bringing to the users in Africa in particular and the world in general.

The review gave special emphasis to the widespread and prevalent diseases in Africa such as malaria and HIV/AIDS, infections which require antibiotics for cure and other chronic non communicable diseases such as diabetes and dysfunctions which are very predominate on males, Erectile Dysfunction(ED).

Software called EndNote X5 was used to arrange the references in order using Vancouver style.

V. SYNTHESIS

a) Magnitude of counterfeit drugs

According to WHO, "counterfeit drugs are defined as those medicines that are deliberately and fraudulently mislabeled with respect to identity and/or sources and include those products with correct ingredients or with wrong ingredients, without active ingredients, with insufficient or excessive amount of active ingredients or with false or misleading labeling"(1). In such regards, there are many types of counterfeit products classified based on their activities. There are products which contain the correct active ingredients and additives in the right amount and they are called perfect counterfeits(1). Likewise, there are also products which contain the right components with an incorrect concentration and/or formulation having defegective quality and they are called imperfect counterfeits. There are also products which are similar to the original product but containing non active ingredients or foreign substances and they are called apparent counterfeits(1). In the same way, products which are apparently similar to the original medicinal product but not having any active ingredients which cause harmful or toxic substances and they are called criminal counterfeits(1).

A study was conducted to know the prevalence of counterfeit drugs in some African and Latin American countries like Angola, Brazil, Cameroun, Central African Republic, Chad, Congo, Ethiopia, Guinea Bissau,

Guinea Conakry, India, Kenya, Madagascar, Malawi, Rwanda, and Uganda. Samples of some drugs were purchased from both from licensed and unlicensed

pharmacies and they were tested for quality(2). The following result was obtained as indicated in the table below:

Table 1 : Therapeutic classes of total and counterfeit samples.

Therapeutic classes	No. (%) of samples	
	Available for analysis	Counterfeit
Antibiotics	76 (34.4)	30 (29.7)
Antipyretics	24 (10.9)	9 (8.9)
Antimalarics	17 (7.7)	6 (5.9)
Antimycotics	13 (5.9)	9 (8.9)
Antihypertensives	8 (3.6)	1 (1.0)
Antianemics	5 (2.3)	4 (4.0)
Spasmolytics	5 (2.3)	2 (2.0)
Diuretics	5 (2.3)	1 (1.0)
Antiacids	5 (2.3)	2 (2.0)
Anti-inflammatories	44 (19.9)	22 (21.8)
Bronchodilators	4 (1.8)	5 (5.0)
Others	15 (6.8)	10 (9.9)

One study has also shown that, out that of 51 artusinate counterfeits which went through spectrometry analysis happened to have other drugs such as paracetamol, sulphadoxine, pyrimethamine, dimenhydrinate, erythromycine, and other active substances which are used for other purpose(7). Some of the counterfeit artusinates were also identified to contain banned substances which are very dangerous to health and some of them were identified as produced in southeast of People Republic of China(7). In another study done in Indonesia in 2006, one fifth of amoxicillin tables and 5 out of 22 samples obtained from pharmacies contained slightly less active substances than required; 50% of co-

trimoxazole tablets had a trimethoprim content which was not meeting BP standards; deviations were up to 20% of the required amount (8).

i. Sources of counterfeit drugs

Highly priced and life-saving drugs, in general, are the target of the counterfeiters(2). Developing countries which do not have controls and sufficient Pharmacovigilance systems are the victims of counterfeit drugs(2). Moreover, provision of service by private sector on availability of anti malarial drugs with lower prices than the formal public health centers has also contributed to the widespread distribution of

counterfeit drugs in Africa(9).The major driving force for counterfeiter to make available counterfeit drugs in the market is known to be for profit(7).

There are some countries like India and china which are playing prominent role in the production of counterfeit drugs which is very much associated with the permissive legislation and inefficient judiciary system, absence of qualified supervising staff and widespread corruption(3, 7). In accordance with WHO assessments, India was the first exporting country among those examined in the present study, with 61 samples (about 50% of which were counterfeits)(2).

ii. *Distribution of counterfeit drugs*

Counterfeit drugs are severely affecting African and other poorer countries and found to be a significant cause of morbidity, mortality and loss of public health confidence. Likewise, the scale of the problem is rising at alarming rate(10) . The prevalence of availability of counterfeit drugs in African and other poorer countries reached about 60%(6). In one study done in pharmacies found in Lagos Nigeria, the prevalence went up to 80%(6). In the same token, two third of anti malarial drugs which were supplied in Ghana in 2009 were counterfeit and 68% of the drug called 'CaortemR tablets are counterfeit in Laos, Burma, Vietnam and Cambodia(11). And one study also showed that 38% to 54% of oral artusinate collected, by convenience sampling, in 2000–2001 and 2002–2003, respectively, were counterfeit(12). Among other examples, counterfeit ARVs which were found in Ivory Cost and DRC can also show the spread, distribution and severity of the problem in African countries(11). But the world circulation of counterfeit drugs is estimated to be 15% and the figure went up to 50% in some part of Africa and Asia(13). A study done in 2006 indicated that the glucose test strips which were manufactured in China were found to give false readings which ultimately urge the patients to take high dose of insulin in 2006(6).

iii. *Health outcomes of counterfeit drugs on diseases and organic dysfunctions*

With regard to the health outcomes of counterfeit drugs, malaria is one of the targets of counterfeiters(7). And malaria is estimated to kill one million people per year and the majority are young children under five in Africa(10). Quality of anti malarial drugs in sub Saharan Africa is a concern as it plays crucial role in the control and management of the disease. Counterfeit or substandard drugs either produce toxic or adverse effects if they are found in higher quantity above the normal dose or result below therapeutic levels if they are found below the standard dose. The availability of lower doses of the drug in the blood stream will bring about resistance as the drug could not kill the parasite efficiently which thereby help the drug resistant parasite to flourish(13).

The effect of using these fake anti malarial drugs will facilitate resistance to malaria parasites and ultimately encourage the spread of drug resistant malaria (11, 12, 14). As a result of this, high-level pyrimethamine resistances seen in Africa which was believed to come from SE Asia(11, 12). In another study done on 30 anti malarial tablets samples containing drugs like chloroquine, quinine, mefloquine, sulphadoxine/pyrimethamine, many kinds of problems were observed such as poor dissolution(in about 50% of the samples) but among which low content of the active ingredients were the most important one from clinical point of view(15).

It is obvious that for a disease like malaria especially in young children, counterfeit drugs which have got either little or no active ingredient can be considered as intentional murder. The patient will not be cured of malaria and there will be a possibility of losing him/her due to death and there is also a danger of contracting disability(16). Though artusinate containing therapy(ACT therapy) was considered as hope to control malaria in Africa and Asia, the counterfeit artusinate are contribution a lot in wide distribution of resistant malaria in the regions(17). This has been persuading the drug to shorten the useful life of the same(18).Likewise, the drugs will develop resistance to the parasites which will urge the care taker to go for newer and more expensive drugs(12, 13, 19).

With regard to antibiotic usage for the treatment of diseases, resistance development is the most important determinant of treatment failure. Among other factors such as low-dose regimen, counterfeit products which do not contain antibiotic at all or containing low dose also played leading role which will finally end up with treatment failure(8). The drug failure is attributable to reduced adherence to therapy, suboptimal dosing, diagnostic and laboratory error, ineffective control and the most important of all is the usage counterfeit drugs(20). Price may be considered as one of the factors for the drugs to be counterfeited. The average price for the active ingredient of amoxicillin is about 26 Euro/kg and duly attracts counterfeits to a great extent(2). In some African countries like Nigeria, counterfeit antibiotics are well known to be available in the market which made the improper use and control of antibiotic difficult(21).

ARVs are also a target for counterfeiters. As most poor countries do not have or insufficient capacity for pharmacological control, it is very difficult for them to halt the health damages that would result due to using these sub standard drugs(22). Though sufficient prevalence data is not available, ARVs which are smuggled from other countries illegally are used in some African countries. As ARVs do have high unit cost and long-term and sustained demand, they are now the major target for the counterfeiters. Some patients are using these counterfeited ARVs to avoid stigma and fear

related to keeping their cases confidential(3). Some studies have shown that there were counterfeit ARVs in Ivory Coast and DRC which signaled the spread, distribution and severity of the problem in African countries(13). With regard to ART, adherence to the treatment is expected to be strictly followed and counterfeit drugs are known to break the chain so that the patient will be liable either to switch to other combinations of ARVs such as second line regimen or death(22).

Among other examples, counterfeit ARVs which were found in Ivory Coast and DRC can also show the spread, distribution and severity of the problem in African countries(11). But the world circulation of counterfeit drugs is estimated to be 15% and the figure went up to 50% in some part of Africa and Asia(13). There was an alert from WHO in 2006 that there appeared counterfeit ARV which was supposed to have three ARVs in fixed dose combinations (zidovudine/lamivudine/indinavir) and which were finally identified to have only one ARV, zidovudine(3). Recently, a counterfeit ARV triple fixed dose combination of stavudine/lamivudine/nevirapine and a dual fixed dose combination of lamivudine/zidovudine have been found in central Africa which is a dangerous hurdle to the treatment of AIDS in sub sharan Africa(10).

Among chronic non communicable diseases, diabetes is one them and it is also the target of counterfeiters. There are many episodes of the dangers of these counterfeit drugs on diabetic drugs. One study done in Singapore on 150 non diabetic patients who were admitted in hospital indicated that seven patients were in coma due to neuroglycopenia which resulted in the death of four patient(1). In relation to diabetes, the blood glucose test strips that are used by most patients to check their blood glucose were also identified to be a target(7).

Drugs which are used for the treatment of erectile dysfunction(ED) are among others where counterfeiters are interested. Between 2004 to 2008 alone, 35.8 million tablets of sildenafil were found in the markets of European countries. As the disease is embarrassing for the patients and the cost of the drug is very high, counterfeiters were very much attracted to the business. Accordingly, the patients who were using these counterfeit sildenafil tablets were exposed to direct and indirect risks. Among direct risks stated in the study is failures of the treatment is predominant. The indirect effects could be seen in the patients that they may lose confidence on their physicians and thereby resulting in not disclosing their case anymore.(1).

As it can be seen in the above data, counterfeit drugs are currently a threat to the management of diseases and organic dysfunctions in particular and the public health system in general. Many health outcomes which range from development of drug resistances to

the susceptible to pathogenic agent to deaths are occurring. Besides, they are also compromising the health programs and policies laid down by countries and other international stakeholders.

VI. LIMITATIONS OF THE REVIEW

The review was supposed to be done to show the health outcomes of counterfeit drugs on many types of diseases and organic dysfunction in Africa. However, the focus is narrowed only to few types of diseases and organic dysfunctions as a result insufficient availability of published articles in freely available websites such as PubMed and others. Even if the problem is rampant and hot issue for Africa and the world, it seems that only few researches were conducted. But this review has vividly indicated to the researchers as an opportunity to conduct many researches which are targeting on the prevalence, magnitude, determinants, sources distribution and health outcomes of these counterfeit drugs and counterfeiters.

VII. CONCLUSIONS AND RECOMMENDATIONS

Among the major health outcomes of counterfeit drugs, development of resistance and toxic action to the body which will ultimately end up with death were mentioned. Studies done on the area also indicated that there are some individuals and countries which are involved in such kind of unethical business. Even if the major driving force to be engaged in this counterfeiting business is known to be for profit, the countries' loose legislation on the registration, import, distribution, manufacturing and retail activities have been identified to play a pivotal role.

The problem is not only confined to one country but it is currently becoming the problem of all nations. Being Africa very poor, the prevalence of the problem seems very huge and therefore African governments do have responsibility to protect its people from being victims of such counterfeit drugs.

As general recommendations, the followings could be laid:

- As the problem is rampant and crosses boarder, there shall be partnership among countries which are responsible for manufacturing and distribution these counterfeit drugs. In such regards, WHO's effort called International Medical Products Anti-Counterfeiting Task Force (IMPACT) should be strengthened.
- Countries should build stringent regulatory authority to control and administer drug and drug related substances in collaboration with custom authorities.
- There should be a clear post market surveillance system that will aid the fast identification of counterfeit and other substandard drugs.

- A strong Pharmacovigilance system which goes from bottom to top should be established so that any adverse/unwanted effects and other drug related problems will be identified.
- Public awareness raising activities should be carried out so that citizens could have a capacity to protect their health from these counterfeit drugs...

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