The Situation of Medicines counterfeiting in Africa
Executive Summary

This background document aims to show the current situation of poor quality medicines in Africa with a particular emphasis on medicines counterfeiting. It discusses the extent of the problem, the impact of low quality medicines and strategies in place to curb them as well as barriers that have been faced in fighting medicines counterfeiting.

There is a dearth of information on the real extent of medicines counterfeiting in Africa. However, the few documented evidence as included in this background document which may serve as useful baseline show that the problem of poor quality medicines, particularly medicines counterfeiting is on the increase and that almost a half of medicines in some regions of Africa may be counterfeit.

This increase in medicines counterfeiting is linked to a variety of causes among which include the chaotic nature of most pharmaceutical markets in Africa, leaky supply chain systems, scarcity and/or erratic medicines supply, high cost of medicines, vested interests both on the part of the regulatory officials and the counterfeiters, weak laws and lack of enforcement of existing laws, high level of corruption, low literacy rates and a lack of coordinated response from key stakeholders such as the health professionals to this illicit crime. The increased diversion of such medicines as antimalarials from the public to the private sector as revealed in a study by Roger Bate show that this may constitute a significant opportunity for trade in counterfeit medicines (Taylor, 2010)

It is difficult to link death or lack of response to treatment to medicines counterfeiting especially in Africa where there is significant under reporting and where other factors such as contamination of drinking water supply, disease complication, malnutrition, failure to complete the course of treatment or even a belief in curses or the supernatural are more likely to be linked to death. However, its impact is obvious when it causes easily observable mass tragedies. Available evidence show that the negative impacts of medicines counterfeiting is enormous. Medicines counterfeiting undermines the ability of Research and Development (R&D) based companies to invest in future innovations, reduces public trust in health care providers and may lead to importation of costlier branded medicines which may be perceived by the patients as been more potent. It causes wastage of scarce resources especially in most of the African countries where patients are forced to pay out of pocket for these ineffective
medicines. It also presents a huge loss to the genuine manufacturers who continually spend more to develop technologies to thwart medicines counterfeiting.

The health risks arising from the use of counterfeited medicines cannot be underestimated. Its effect ranges from treatment failures, development of adverse drug reaction, increased disease severity, development of complication, development of drug resistance to even deaths.

Significant steps have been taken to fight medicines counterfeiting by some African governments and their regulatory bodies, health professional organisations and international organisations such as the World Health Organisation (WHO) and INTERPOL. However, there remains a need to ensure a zero tolerance to medicines counterfeiting as it appears that curbing this illicit crime is primary to any significant improvements that may be made in the millennium development goals. Health professionals are uniquely positioned in this fight and must rise up to the challenge to increase the awareness of this problem and implement definitive strategies towards curbing it.
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1. Introduction

The quality of medicines are determined by factors such as the raw materials used, manufacturing environment, formulation, manufacturing process, equipment, technical know-how for production and packaging of the product, transportation and storage conditions. Quality specifications are usually set by the manufacturers and are published in Pharmacopoeias (USP, 2010). Poor quality medicines refer to medicines (legally registered, generics or counterfeits) which do not meet the official specifications for strength, quality, purity, packaging or labelling (USP, 2010).

Medicines quality is increasingly becoming of concern in many parts of the world due to the recent increase in the cases of medicines counterfeiting. About 61% of individuals included in a survey conducted by Pfizer on medicines counterfeiting believe that it presents a serious problem in their countries (FIP, 2010c). The threat of counterfeiting appears to be invisible due to its nature as well as the neglect it has suffered over the years from the stakeholders involved in the pharmaceutical supply chain (Lybecker, 2007). This problem is particularly important in many developing countries which are faced with an increased burden of both communicable and chronic disease among other numerous public health issues. The health workforce in developing countries is overburdened, in short supply and are faced with the problem of poor quality medicines.

Poor quality medicines may be difficult to recall in pharmaceutical supply chains that lack tracking systems as seen in the case of batches of ringers lactate infusion donated to relief agencies in Darfur, that were contaminated with a fungal growth. Six months after the World Health Organisation issued a recall of the infusions, less than 15% (2200 of 15000 bottles) of the contaminated product had been located (Caudron et al. 2008). Although the cited example may not be a case of counterfeiting, it clearly shows that it is difficult to retrieve medicines once they have gained access into the distribution chain.

Chaotic drug distribution systems, leaky supply chain systems, scarcity and/or erratic medicines supply, high cost of medicines, vested interests both on the part of the regulatory officials and the counterfeiter, weak laws and lack of enforcement of existing laws, ignorance or low literacy rates, pervasive poverty, poorly equipped laboratories, under-funded regulatory authorities as well as poor handling and manufacturing practices and high level of corruption in the health care system has been identified as the common reasons for
the preponderance of counterfeit medicines in such countries as Nigeria (Erhun et al. 2001). The high cost of medicines is worsened by high import tariffs on drugs in such countries as Nigeria, Congo, Morocco and Zimbabwe among others which have tariffs of 15% or more (Bate and Boateng, 2006 and Wertheimer and Norris, 2009). This constitutes a significant financial burden to the patients especially where they are forced to pay for the medicines out of their pocket (Wertheimer and Norris, 2009).

Medicines obtained from illicit sources are most often counterfeits, for instance the Pharmaceutical Manufacturers Group of the Manufacturers Association of Nigeria (PGM-MAN) revealed that medicines sold in open street markets accounted for almost half of counterfeit medicines in Nigeria while Patent Medicine Vendors (PMV) accounted for 32.8% and that 58.8% of medical doctors in Lagos state sourced their medicines from open markets (PGM-MAN, 2001 cited in Peterson and Obileye, 2002).

Medicines counterfeiting is increasingly becoming like the worldwide narcotic trade in that in majority of the cases, the raw materials are obtained from one country, formulated into tablets or capsules in another country, packaged in a different country and then shipped through several countries before arriving at its final destination (Lybecker, 2007). In Egypt for instance where about 10% of medicines sold are believed to be counterfeit, following the recent warehouse raids, a large amount of counterfeit medicines purporting to treat all kinds of illness were confiscated (CNN Money, 2009). These medicines were thought to originate from China and passed through Syria before arriving in Egypt (Egypt today, 2009). Profits accruing from medicines counterfeiting equates to and may even supersede that of the narcotics trade, yet it is subject to lesser penalties in some countries (Lybecker, 2004). For instance; one gram of cocaine may be valued at $100 while some counterfeited medicines may sell for up to $3,000 per gram (Kontnik, 2003). In Kenya, about Sh 4 billion (USD $64.5 million) is estimated to be spent by its government on counterfeit medicines while convicted counterfeiters are subject to only up to Sh 5, 000 (USD$80) fine (Mbogo, 2008). Another challenge to the conviction of the counterfeiters is that in some of the cases the persons involved may be children who are unaware of the public health threat of counterfeiting and cannot be arrested (IRIN, 2010c).

Aside from the personal monetary gains that may be obtained from medicines counterfeiting, there is some evidence that funds raised from such crime may be geared towards terrorism or

Medicines are a particular target to counterfeiters because they are of a low bulk, yet are of very high value (Akunyili, 2006b). Poor quality medicines can also result from such factors as degradation of medicines when exposed to tropical weather conditions as well as inadequate quality assurance/control on the part of the manufacturers. Furthermore, the problem of a lack of human and financial resources needed to tackle the problem of poor quality medicines creates a scenario which is conducive for the proliferation of trade in counterfeit and sub-standard medicines (Caudron et al, 2008). Conflicts in the form of wars such as the case of Liberia create room for more influx of counterfeit medicines (Nyanko, 2007). The lack of agreement among stakeholders on a universal definition for counterfeit and substandard medicines has hindered initiatives which are aimed at curbing medicines counterfeiting (Caudron et al, 2008).

In an attempt to differentiate counterfeit drugs from substandard medicines which are both categories of poor-quality medicines; the World Health Organisation (WHO) defines a counterfeit drug as ‘a medicine, which is deliberately and fraudulently mislabelled with respect to identity and/or source’ (Wondemagegnehu (1999) cited in Newton et al. (2006a). Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct or wrong ingredients, without or with insufficient active ingredients or with fake packaging’ (World Health Organisation 2010). It has also been found that counterfeiters copy or imitate existing products, but they also manufacture products which they have invented, and are not normally available (IMPACT, 2008). The WHO defines substandard drugs as ‘genuine drug products which do not meet quality specifications set for them’ (Smine, 2002). Substandard medicines are approved and legally manufactured, but does not meet all quality criteria. It may pose a significant health risk, but should not be regarded as counterfeit. However, all counterfeits are, by nature, at high risk of being substandard (IFPMA, 2010). The WHO definition of counterfeit and substandard medicines is supported by countries where people suffer terribly from counterfeit drugs, such as Gambia, Ghana and Nigeria (Harris, 2010).
2. Definition of Counterfeit and substandard medicines by country; a focus on Africa

Due to the varying nature as well as the complexity of medicines counterfeiting in some countries, the definition of counterfeit medicines varies from country to country. For instance; The National Agency for Food and Drug Administration and Control (NAFDAC) - Nigeria’s regulatory agency - has identified counterfeit drugs to be those with;

- same quantity of active ingredient as the genuine brands which are clones that are unlikely to produce the desired therapeutic effects due to differences in their formulation and bioavailability when compared to the genuine brands

- Medicines with insufficient or without active ingredient, expired medicines as well as toxic or ineffective herbal preparations and medicines lacking the name and address of the manufacturer (Akunyili, 2004). Medicines which are not certified and registered by NAFDAC are also regarded as counterfeits (Akunyili, 2004)

The Nigerian Counterfeit and Fake Drugs and Unwholesome Processed Foods (1999 Miscellaneous Provisions) Decree defines a fake drug as:

a. “any drug product which is not what it purports to be; or

b. any drug or drug product which is so coloured, 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 labelled 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

c. any drug or drug product whose container is so made, formed or filled as to be misleading; or

d. 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 the Agency in accordance with the
provisions of the Food, Drugs and Related Products (Registration, etc.) Decree 1993, as amended."

The definition of counterfeit medicines by Liberia Medicines and Health Products Regulatory (LMHRA) is also very similar to that of the WHO while it defines a substandard medicine as one that does not comply with the quality standards by the LMHRA. It further defines adulteration as tampering with a product in such a way as to affect the authenticity of the original product (Smine et al, 2009).

By these definitions; it is quite difficult to determine the extent of medicines counterfeiting in different countries. This is because although most poor quality medicines that have been detected were also found to be both substandard and counterfeit, it is flawed to conclude that a product is counterfeit as a result of failure to comply with quality standards. Additional inspection of the packaging of the drugs may be helpful in determining which of the products are counterfeit and those that are substandard. This may be limited by the sophisticated nature of medicines counterfeiting as even complex holograms have been successfully copied by the counterfeiters. However, forensic examinations of trademarks or product designs can be carried out to differentiate counterfeited products from substandard products as well as to determine the source of the counterfeited products (Newton et al, 2008). This distinction is vital since the reasons for their production and potential countermeasures are different. For example, the strategies to combat substandard medicines may be more straightforward. In this instance, focus can be placed on the manufacturing and quality assurance processes in production to resolve these issues which is not the case with tackling medicines counterfeiting (Newton et al, 2010).

Aside from the country definitions of counterfeit medicines which are rooted in a public health perspective, some other organisations define counterfeiting from an intellectual property right infringement point of view. The World Trade Organisation (WTO) Agreement on Trade Related Aspects of Intellectual Property defines counterfeit trademark goods as “meaning any goods, including packaging, bearing without authorisation a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation” (The World Trade Organisation Agreement on Trade Related Aspects of Intellectual Property
WHO research into the use of the term “counterfeit” revealed that majority (34) of the member states used the term “counterfeit” in their national legislation. Other terms used include “falsified”, “illicit”, “illegal”, “unregistered”, “unauthorized” and “adulterated”. Besides these variations in terms; the meaning of counterfeit medicines in some of the national legislations includes unauthorised medicines, substandard medicines and intellectual property infringement. The implication of these is that what may be considered a counterfeit in one country may not be viewed same in another country (Deisingh, 2005).

3. History of medicines counterfeiting

Medicines counterfeiting is often referred to as the ‘second oldest profession’ (Lybecker, 2008). Its history dates back to the first century in Greece when Dioscorides first classified drugs by their therapeutic use and warned of the dangers of adulterated drugs as well as how they could be detected (WHO, 1999a cited in Newton et al, 2006a). The mid 19th-century witnessed a widespread adulteration of medicines especially quinine which led to the establishment of the Code of Ethics for Pharmacists and guides on the detection of counterfeits in the United States of America (Newton et al, 2006a). Since then there have been anecdotal reports of tragedies resulting from the use of poor quality medicines. In Nigeria for instance, medicines counterfeiting was first observed in 1968 when there was a deregulation of crown agents as sole distributors of medicines (Akunyili, 2007). This led to the promulgation of the Food and Drug Decree No. 35 in 1974. Owing to the global economic recession at the time and the consequent devaluation of the Nigerian currency (Naira); most drugs became unaffordable to the majority of the population leading to the issuance of import license for drugs (NAFDAC, 2002-2009). However, the implementation and issuance of Import licenses were based mainly on political patronage leading to its issuance to unqualified persons who lacked adequate knowledge of drugs. This situation coupled with an increase in demand for drugs and continued irrational drug use led to increased importation of fake drugs by non-professionals since they were cheaper than genuine drugs (Peterson and Obileyie, 2002). It then became obvious that the existing decree could not tackle the problem of drug quality in Nigeria and the Counterfeit and Fake Drugs Decree No.17 of 1989 was then promulgated. This established the Task force which is an arm of NAFDAC and was later replaced with Decree 25 of 1999 that included a stricter penalty for forfeiture and an option of N500, 000 fine for medicines counterfeiting as well as
empowering the Task force to close down the open drug markets and all unregistered premises (Orivri, 2009) (Peterson and Obileye, 2002). In East African Community (EAC) countries such as Kenya, the increased incidence of medicines counterfeiting has been worsened by a lax in tariffs and administration restrictions on the circulation of products within its market, making unscrupulous entrepreneurs to exploit the situation.

Despite the importance of tackling medicines counterfeiting, it was not given international recognition until 24 years ago when it was first discussed at an international health meeting; the WHO Conference of Experts on Rational Drug Use (WHO, 2006). In 1988, the World Health Assembly issued a resolution (WHA41.16) against counterfeit and substandard pharmaceuticals requiring initiation of programmes to prevent and detect poor quality drugs (Newton et al, 2006a). In 1992, the first international meeting on counterfeiting was held in Geneva which recommended a collaborative effort to help curb the problem and defining a counterfeit drug. In 1994, resolution WHA 47.13 was adopted to help member states in their effort to solve the problem. In 1995, World Health Organization Division of Drug Management and Policies (DMP) and the Action Programme on Essential Drugs (DAP) established the DMP-DAP project with the assistance of the Japanese government in pursuance of resolution WHA47.13. This led to the organisation of a workshop in 1997 with outcomes of recommendations for international and national actions against counterfeiting, setting up of a database containing information on anecdotal reports from the literature and on reports from Drug Regulatory Authorities and industries as well as the publication of guidelines for development of measures to combat counterfeit drugs in 1999 (WHO, 1999a). Since then additional workshops for instance in Japan and Viet Nam, training and country studies on medicines counterfeiting for instance in Viet Nam and in Myanmar on have been carried out by the WHO. In a bid to crack counterfeiting, WHO held a conference in Rome in 2006 which led to the Declaration of Rome and the formation of International Medical Products Anti-counterfeiting Taskforce (IMPACT) which is aimed at forming a collaborative effort among a range of stakeholders in order to curb medicines counterfeiting. IMPACT focuses on major technical areas which have been identified as needing action nationally and internationally; legislative and regulatory infrastructure, regulatory implementation, enforcement, technology development for detection of counterfeits and technology transfer to developing countries as well as communication of risk and innovations/strategies aimed at curbing counterfeiting (WHO, 2010a).
What is now unique about medicines counterfeiting when compared to what was reported prior to the 20th Century is the international nature and scope of the problem as well as the sophisticated technology and strategies employed in this crime (Forzley, 2005).

4. **Extent of poor quality medicines in Africa**

In trying to describe the extent of medicines counterfeiting as one category of poor quality medicines, it is important to note that the majority of the evidence available is anecdotal. This is probably due to either the limited number of peer reviewed studies to estimate the scale or concealment of the problem by some legitimate manufacturers in order to avoid adversely affecting their reputation and public trust in medicines (Shakoor et al, 1997). Much of the information on the quality of medicines is published in the grey literature such as in newspapers and internet articles instead of in the scientific literature, suggesting significant under reporting or a lack of properly designed studies. Thirty eight studies conducted in different African countries which were based on quantitative field studies conducted to determine the proportion of collected samples which did not meet pharmacopoeial criteria in order to ascertain the incidence of poor quality medicines in such areas were identified; Taylor et al. (2001), Shakoor et al. (1997), Maponga and Ondari (2003), Bate at al, (2008), Bate at al. (2009a), Kaur et al. (2008), Gaudiano et al. (2007), Eichie et al. (2009), Nnamdi et al. (2009), Onwujeke et al. (2009), Atemnkeng (2007), Odeniyi et al. (2003), Amin et. al (2005), Sowunmi et al. (1994), Babalola et al. (2004), Okeke and Lamikanra (1995), Odunfa et al. (2009), Esimone et al. (2008), Patel et al. (2009), Ogwal-Okeng et al. (2003), Odili et al. (2006), Nazerali and Hogerzeil (1998), Kenyon et al. (1999), Kayumba et al. (2004), Basco (2004), Tipke et al. (2009), Ofori-kwaye and Gaye (2008), Atemnkeng (2006), Ifudu, (1989), Bate and Hess (2010), USP/USAID (2009), Ofonaike et al. (2007), Hebron et al. (2005), Risha et al. (2002), Getu and Awot (2010), Minzi et al. (2003), Abdi et al. (1995) and Aka et al. (2005). Fourteen of these studies (Taylor et al, 2010, Shakoor et al, 2007, Bate et al, 2009a, Eiche et al, 2009, Nnamdi et al, 2009, Onwujeke et al, 2009, Odeniyi et al, 2003, Sowunmi et al, 1994, Babalola et al, 2004, Okeke and Lamikanra (1995), Odunfa et al. (2007), Esimone et al. (2008), Ifudu (1989) and Ofonaike et al. (2007) were conducted in Nigeria. Most of the studies only tested the content of active ingredient and dissolution rates. Only four of the studies (Sowunmi et al, 1994, Babalola et al, 2004, Okeke and Lamikanra, 1995 and Nazerali and Hogerzeil, 1998) conducted further bioavailability studies. Two studies; USP/USAID (2009) and Hebron et al. (2005) conducted impurity tests. Only nine of
the studies employed random sampling while the majority used convenient sampling or unclear sampling techniques. Five of the studies (Kaur et al, 2008, Hebron et al, 2005, Risha et al, 2002, Abdi et al, 1995 and Minzi et al, 2003) were conducted in Tanzania. One study; Oforo-Kwakye et al, 2008 was conducted in Ghana. One study (Aka et al, 2005) was conducted in Cote d’Ivoire. Gaudiano et al. (2007) involved samples from Congo, Burundi and Angola. Bate et al. (2008) tested samples obtained from Uganda, Nigeria, Ghana, Kenya, Rwanda and Tanzania. Other studies conducted in Kenya to determine the extent of medicines counterfeiting includes Kibwage et al, (1992), Roy (1994), Amin et al. (2005) and Atemnkeng (2006) which involved samples from Congo and Kenya. One study identified; Getu and Amos (2010) tried to determine the extent of poor quality medicines in Ethiopia. One study; Bate and Hess (2010) compared the extent of poor quality medicines (counterfeit and substandard in two major cities of Nigeria and Ghana; Lagos and Accra. This study also compared the incidence of medicines counterfeiting in 2007 to that in 2010 in these cities. One of the studies; Bate et al. (2009a) included a quantitative survey of doctors, pharmacists, healthcare workers with the aim of assessing how aware they were of the problem of poor quality medicines (counterfeit and substandard) and how this influenced their professional behaviour. The researchers explored how these attitudes impeded or encouraged regulatory initiatives to eradicate poor quality medicines. Two other studies Patel et al. (2009) and Odili et al. (2006) explored stakeholder perceptions of drug quality in South Africa and Nigeria respectively. None of the studies identified clearly distinguished between counterfeit and substandard medicines. Studies conducted to determine the extent of medicines counterfeiting or the prevalence of poor quality medicines were also identified in other African countries such as Madagascar, Senegal, Uganda, Sudan, Burkinafaso, Cameroon, Zimbabwe and Botswana.

Studies aimed at determining the extent of poor quality medicines, where available are often limited to a few drug classes and test medicines for a narrow set of problems such as antimalarials and antibiotics. Thirty one of the studies that were identified included antimalarials, 6 of the studies involved anti-bacteria, 4 involved anti-tuberculosis. Only a few of the studies involved a relatively wider range of therapeutic class; Taylor et al. (2001) sampled anti-malarials, anti-bacteria, anti-tuberculosis, antifungal and anthelminthic. Bate at al (2009a) sampled anti-malarial, antibacterial, and anti-tuberculosis. Ifudu (1989); the first quantitative study aimed at determining the prevalence of poor quality medicines in Nigeria.
sampled purgatives, benzodiazepines, antipsychotics, multivitamin/vitamin B and some haemopoetic medicines. Eichie et al. (2009) and Ofonaike (2007) were the only two studies that involved solely analgesics.

The majority of the studies conducted in developing countries in order to determine the prevalence of medicines counterfeiting show that about half of the drugs tested were substandard. In Nigeria for instance, the percentage of samples failing standard tests ranged from about 32% to 48% in the majority of the studies. Only the study by Bate et al. (2009a) showed a smaller proportion (18%) that failed the standard tests. Even so; 18% is unacceptable as the dangers which may result from it cannot be underestimated. This reduction observed from Bate et al. (2009a) may have been due to the methodology used to determine the chemical constituent of the medicines or the small sample size (140 treatment packs). A repeat study by Bate and Hess (2010) showed that overall failure rates in Lagos had fallen from about 32% observed in 2007 to about 13% in 2010. Similar findings were observed in Accra between 2007 and 2010. However, these findings may have been due to the small sample sizes involved; 22 samples in 2007 and 94 samples in 2010 and therefore may not be conclusive without larger studies conducted to confirm such observations.

A study by Taylor et al. (2001) showed that 48% of randomly sampled drugs (antibiotics and antiparasitic) from Nigeria failed to comply with set pharmacopoeial standards seemed to be the first to employ random sampling and tried to appropriately describe the methods used (Newton et al, 2006a). Aside from this, 8 other studies (Ifudu, 1989, Atemnkeng, 2006, Bate and Hess, 2010, Hebron et al, 2005, Bate et al, 2009a, Bate et al, 2008, Kaur et al, 2008 and Onwujekwe et al, 2009) employed random sampling with the majority using convenient sampling which may have affected the validity of the findings arising from such studies.

Earlier studies in Kenya by Kibwage et al. (1992) and Roy (1994) revealed that about 46% and 31% respectively of different drugs samples obtained from Kenya were substandard while more recent studies show that about 40% of medicines sampled from Kenya failed quality tests Amin et al, (2005). The Kenyan association of pharmaceutical industries estimates that about 30% of its drug market may be counterfeit (Keshi, 2008). Another study carried out to determine the prevalence of substandard drugs include the study by Atemnkeng et al. (2006), which showed that about 37.5% of antimalarials (artemisinin derivative) randomly collected from pharmacies in Peoples’ Republic of Congo and Kenya failed quality
tests for active ingredients. This high prevalence in Nigeria and Kenya is similar to the findings of other studies conducted in other African countries; Ethiopia, Tanzania, Rwanda, Cameroon, Angola, Burundi, Uganda, Madagascar, Senegal, Zimbabwe, Sudan, Burkinafaso and Botswana; with almost half of the samples collected in this region been shown to fail the necessary tests. A pilot study by Aka et al. (2005) showed that about 20% of anthelminthic medicines sampled from four major cities in Cote d’Ivoire were counterfeits. In Ouagadougou, about one in five pharmaceutical drugs bought on the street is counterfeit and is usually sold with no prescription and no expiry date (IRIN, 2010a). These estimates and findings are indicative of an unsatisfactory and potentially hazardous situation.

Nigeria has been stated to be the second largest producer of counterfeit medicines, accounting for about 23% of counterfeit medicines distributed worldwide after India which is thought to account for about 35%; and Pakistan, 13.3% (Datta, 2003 cited in Lybecker, 2004). International health care organizations have estimated that in Africa as a whole, 25 to 50 percent of the pharmaceutical market is counterfeit, with Nigeria being the most affected, accounting for 50 percent of the total sales of fake drugs Nyanko (2007).

From the results of these studies it is difficult to exactly state the actual extent of poor quality medicines or to compare the findings in different countries due to non-uniformity in the methods employed in these studies, limited sample size and sampling of specific drug classes in most of the studies identified. However, it seems that the WHO’s estimate of about 10% of the global Pharmaceutical commerce been counterfeit and that about 30% of medicines in regions like Africa may be counterfeit may to some extent be reasonable (WHO, 1999a). WHO (2003) cited in Morris and Stevens (2006) showed that a survey by the WHO of the quality of antimalarials in seven African countries (Gabon, Ghana, Kenya, Mali, Mozambique, Sudan, and Zimbabwe) revealed that between 20% and 90% of the products failed quality testing. This included chloroquine-based syrup and tablets with failure rates ranging from 23% to 38% and about 90% of the sulphadoxine/pyrimethamine tablets were found to be substandard (Maponga and Ondari, 2003). Between 1991 and 1993, 519 samples were collected from private, public and non governmental drug outlets and illegal markets in three African countries by the WHO; 429 of the samples were tested in independent laboratories; out of which 77 (18%) were discovered to be substandard (WHO 1995 cited in WHO, 1999b). Sixteen of the samples that failed quality tests did not contain any active ingredient, and were therefore deemed counterfeit (WHO 1995 cited in WHO, 1999b).
(2009) in trying to compare technologies to test for substandard medicines in field settings found that 41-47% of antimalarial, antibiotic and antimycobacterial drugs sampled from pharmacies in 5 African countries failed at least one quality test (Bate, Tren and Hess, 2009 cited in Bate, 2009). About 20% of medicines sampled from Cameroon were found to be substandard (Taylor and Craig, 2009)

The WHO started collecting data on medicines counterfeiting in 1982; most of which were from developing countries (Forzely, 2005). Between 1984-1999, the WHO received about 771 reports of medicines counterfeiting from different countries; 78% of these were from developing countries while from January 1999 to October 2002, 46 confidential reports were received from 20 different countries; 60% from developing countries and 40% from developed countries (Akunyili, 2003). Almost a third of reported counterfeited medicines did not contain active ingredients. About 20.2% had incorrect quantities of active ingredients, 21.4% included wrong ingredients, 15.6% had the correct quantities of active ingredients but with fake packaging, 1% was copies of the original and 8.5% contained high levels of impurities and contaminants (Patel, 2006). Comparing the trend in reports between 1984 and 1999 with that between 1999 and 2002 reveals that although the problem of poor quality medicines is prevalent in regions such as Africa, there has also been an increase in counterfeiting in the developed countries (AIPM, 2007 cited in Lybecker, 2008). It must be noted that the information contained in the WHO database may not be completely accurate as it may contain some reports that have not been validated (Ham, 2003).
Drugs found in places such as the streets and open markets may be of lower quality since they are often not well regulated; for instance, Low level providers (patent medicine vendors) accounted for 78% of suspect medicines in Onwujekwe et al. (2009) and 90% of medicines found to be substandard in Tipke et al. (2009) were obtained from illicit outlets (markets, street vendors and shops). The National Agency for Food and Drug Administration and Control (NAFDAC) reported in 2006 that the incidence of counterfeit medicines had been reduced to about 16.7% from previous values of as much as 70% (Taylor and Craig, 2009). However, this figure is believed to have been made worse by the increased incidence of about 40% at the open market located in Onitsha, popularly known as head bridge market (PSN, 2007, Okoye, 2007 cited in Milissa McGinnis, 2010). Other open drug markets in Nigeria which may have contributed to the high prevalence of substandard and counterfeit medicines include Ariaria market (alleged in 2002 to have about 75% of drugs in stock as fake), Sabon Gari market, Kano (survey by NAFDAC showed about 90% of outlets in this market are unregistered) and Idumota market, Lagos (PSN, 2007). This raises a question of whether
such African countries as Nigeria where these open drug markets are existent should devote more efforts in curbing counterfeiting in areas perceived to have a higher prevalence.

Disparities also exist between the rural and urban areas in terms of the quality of medicines available. In most African countries, poor quality medicines are more prevalent in the rural areas which are often less regulated than in the urban areas. This was also revealed in the study by Onwujekwe et al. (2009) which found that poor quality medicines were more common in the rural areas. This means that the inhabitants of the rural areas who are usually poor with low socio-economic status receive the lowest quality of treatment as they often buy their medicines from the Patent Medicine Vendors (PMV) and as such urgent measures are needed to remedy these most disadvantaged people in resource poor countries who are largely affected by the menace of counterfeiting.

Furthermore, the trend of medicines counterfeiting seems to vary between regions. For example, the majority of counterfeited medicines in developing countries such as Nigeria are life saving medicines such as antibiotics, anti-malarials and anti-infectives (Bate et al, 2009a). A review; Kelesidis et al. (2007) showed that counterfeit and substandard forms of antimalarials and antibiotics have been found in Nigeria (see table 1 below). This does not necessarily mean that counterfeit forms of other medicines not mentioned here do not exist in Nigeria as there is a probability that they may not have been sampled for testing. In Tanzania, counterfeit forms of prednisolone, dihydroartemisinin, sulphadoxine-pyrimethamine, amodiaquine and chloroquine have been detected. In Ghana and other African countries, counterfeit forms of antibiotics, antimalarials and anti-TB medicines are common place (Milissa McGinnis, 2010). Contrary to expectations, it is not always the most expensive drugs that are counterfeited; economies of scale may make counterfeiting of even the cheapest drug worthwhile. This is shown from the results of Ofonaike et al. (2007) where poor quality medicines such as paracetamol and chloroquine were found and Tipke et al. (2009) where chloroquine samples formed a significant proportion of samples that were of poor quality. Products that are counterfeited often include both locally made as well as imported medicines and not limited to any particular drug class (IRIN, 2010d; Cockburn, 2005). Recent drug seizures by Interpol in Egypt showed that all classes of drugs were counterfeited (WHO, 2010b). Fake Viagra™ tablets made by combining ingredients in a cement mixer were also discovered in Egypt (NST online, 2007 cited in Milissa McGinnis, 2010).
Table 1: Counterfeit and substandard forms of medicines that have been found in Nigeria

<table>
<thead>
<tr>
<th>Drug class</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antimalarials</td>
<td>artemisinin derivatives: dihydroartemisinin and artemether-lumefantrine, Others: Chloroquine, Sulfadoxine-pyrimethamine, Quinine sulphate and Halofantrine</td>
</tr>
<tr>
<td>Antibiotics</td>
<td>Penicillins: Ampicillin, Ampicillin-clavulanate, Ampicillin-cloxacillin, Amoxicillin, Cloxacillin) Macrolides: Erythromycin Sulphonamides (Cotrimoxazole, Sulphamethizole), Quinolones (Ciprofloxacin), Aminoglycosides: Gentamycine and Néomycine Others: Chloramphenicol, Tétracycline, Metronidazole</td>
</tr>
</tbody>
</table>

Adapted from Kelesidis et al. (2007)

5. Impact of poor quality medicines

There are no reliable data on the mortality and morbidity arising from the use of poor quality pharmaceutical products in Africa and other developing countries. The effects go unnoticed except when it causes easily observable mass tragedies (Erhun et al. 2001). When data on extent and impact of counterfeiting are available, they are often limited as only 5-15% of the 191 WHO member states report cases of counterfeiting and generalisations made from such reports may not be accurate (Newton et al, 2010).

Only three journal articles were found to describe the impact of poor quality (counterfeit and substandard medicines); Morris and Philip (2006), Fenoff and Wilson (2009) and Newton et al. (2006a). While these articles focused on mass tragedies in the form of death attributed to the use of poor quality medicines, Morris and Stevens (2006) and Newton et al. (2006a) also included other consequences such as development of drug resistance.

5.1 Economic Consequences:

Medicines counterfeiting undermines the ability of Research and Development (R&D) based companies to invest in future innovation (Morris and Stevens, 2006). It also negatively affects the R&D companies by reducing their sales; for instance, in Nigeria, sales volume for Panadol™ and Glaxo's antimalarial; Halofantrine (Halfan™) doubled in 2002 compared with
2001 when medicines counterfeiting was considered to be more prevalent (Naik, 2004). Similarly the sale of Glucophage™ by Merk have fallen to 75% since 2008 mainly due to medicines counterfeiting (Bennett, 2010).

Counterfeiting also causes serious harm to the reputation of the genuine pharmaceutical manufacturers and makes them liable to any harm that may result from consumers ingesting counterfeit medicines. In addition to this, counterfeiting increases the expenditure of the legitimate manufacturers as they have to constantly develop new strategies to thwart counterfeiting. Through such avenues as parallel importation, counterfeiting may affect other markets such as the United States (US) market which puts the industry’s most lucrative market at risk (Lybecker, 2007). In addition to these, medicines counterfeiting reduces public trust in health-care providers, undermines the credibility of health systems, dispensing processes and the government. This may lead to non adherence of patients to their medicines or importation of costlier branded medicines which the patients consider to be more potent (Seiter, 2009). Seiter (2009) tried to quantify the cost of ineffective anti-malarials. From previous estimates, he estimated that in a country of about 20 million people, there may be 4 million anti-malarial treatments. Among these, there may be an estimated 800,000 cases treated with poor quality anti-malarials resulting in up to 4,000 childhood deaths. From his calculations, an average worker spends about half a day working to pay for these ineffective drugs. In total, about 3.2 million working days is spent working to obtain money for these illicit medicines. One can therefore imagine the indirect financial losses and the huge cost of a fake medicine which is far in excess of its face monetary value. The calculations and estimates by Seiter, 2009 may be lower than the real costs of these medicines as they do not take into consideration the possibility that in such endemic regions as the sub-Saharan Africa, one patient can be treated on multiple occasions per year for malaria and the chances of treating the individual with an ineffective drug are the same each time treatment is received (Willyard, 2010).

Furthermore, Counterfeiting can be detrimental to national economies. This is because genuine manufacturers compete with illegal manufacturers who do not pay any import duties and sales tax of the medicines they sell (Fenoff and Wilson, 2009). In addition this hampers trade relations between countries as it may result in trade restrictions. An example is the ban of sale of ‘Made in Nigeria’ pharmaceutical products which were sold in neighbouring countries before 2001; a time when Nigeria seemed to be a major hub for medicines
counterfeiting (Fenoff and Wilson, 2009). Between 2001 and 2005, 30 Indian and Chinese pharmaceutical companies and one Pakistani company that were confirmed to be manufacturing counterfeit drugs were banned from exporting drugs to Nigeria (Akunyili, 2005a). Counterfeiting repels foreign investment in the countries concerned, reduces profits for developing countries by reducing incentives for further research and diverts resources for genuine treatment (Lybecker, 2007).

Drug suppliers are also endangered by this menace as it has been shown that consumers have a particular preference for these counterfeited medicines (Rozendaal, 2001 cited in Lybecker, 2007). There is no doubt that money wasted by patients who buy these illicit medicines can be equated to several days’ wages considering the low socio-economic status of most of these vulnerable patients in such resource poor countries as Nigeria where about 34.1% of the population are below the poverty line (Seiter, 2009 and UN Human Development Report, 2008 cited in IMPACT (2009). “If substandard and counterfeit drug use is not curbed, economies which are now fragile can crack under the burden of unfunded future liabilities. This is just not a health emergency; it is a macroeconomic pandemic in the making” (Wertheimer and Norris, 2009).

5.2 Health Risks:

Roy (1994); Abdi et al. (1995); Arya (1995); Kron (1996) focused on treatment failure as a consequence of poor quality medicines use while seven others; Milan (1987); Pandya (1988); Masland and Marshall (1990); Silveman et al. (1990), Okuonghae et al. (1992), OgohAlubo (1994) and Hanif et al. (1995) showed that consumption of poor quality drugs could result in serious damage to the patients’ health or even death.

Medicines counterfeiting is partly responsible for the doubling of malaria deaths over the last 20 years according to Dora Akunyili, former head of the Nigerian’s National Agency for Food and Drug Administration and Control (Morris and Stevens, 2006). This is evidenced by the fact that 8 of the 12 major antimalarial drugs in use have been reported to have been counterfeited (Newton et al, 2006a). It appears that until the distribution of poor quality medicines is tackled, the efforts of new drug discovery and development will continually be rendered futile. This also means that resistance at the population level renders legitimate drugs less effective, even amongst patients who have not used fake and/or poor-quality
medicines (Bate at al. 2009a) causing a switch to second or third line medicines which are usually more expensive and more toxic (Centre for Global Development, 2010).

Although it is a difficult task to trace illness and death to counterfeit or substandard medicines, evidence show that poor quality medicines pose significant threats to consumers as they cause adverse reactions, lack of successful treatment and possibly death (Nsimbba, 2008). Evidence of this can be seen from previous experiences in some developing countries such as the death of about 100 children in Nigeria in 1990 following the ingestion of a cough mixture which was diluted with a poisonous solvent, diethylene glycol (DEG) (Deisingh, 2005). Eighty-four more children died in Nigeria between late 2008 and early 2009 due to the consumption of diethylene glycol-contaminated teething medicine “My Pikin Baby Teething Mixture”, distributed by the NAFDAC-licensed Barewa Pharmaceuticals (Polgreen, 2009; Eboh, 2008, Harris, 2008, Mbachu, 2009 cited in Milissa McGinnis, 2010). Other countries that have experienced similar catastrophic incidents include the United States of America, South Africa, Spain, Austria, India, Argentina, Haiti, Bangladesh, Panama and China (Wikipedia, 2010b). Another catastrophic example is the death of about 2,500 people resulting from the consumption by about 60,000 people of vaccines donated by Nigeria to Niger during a meningitis epidemic which were later found not to contain any active ingredient (Fenoff and Wilson, 2009). Other incidents which have been attributed to the use of poor quality medicines include the report from three Nigerian hospitals of cases of adverse reactions from the use of infusions which were contaminated with micro organisms. Also, 147 out of the 149 water for injections analysed from these hospitals were found to be unsterile (Akunyili, 2006a). Two children were reported to have died as a result of fake adrenaline administered to them during an open-heart surgery at University of Nigeria Teaching Hospital, Enugu (Akunyili, 2007). Medicines counterfeiting have also been implicated in some cases of liver damage, kidney failure and heart damage in Nigeria (Kapp, 2002 cited in Yar, 2008). The WHO estimates that about 100, 000 Africans die annually from the consumption of counterfeit medicines and that about 200,000 deaths per year could be avoided if illnesses are treated with only medicines of high quality (All West Africa, 2009b; International Council of Nurses, 2005).

Counterfeiting can lead to drug resistance. The Netherlands Leprosy Relief and Royal Tropical Institute states that about 305 samples of TB medicines tested in Nigeria did not pass the tests and may be a major contributor to the development of multidrug resistance
tuberculosis (MDRTB) (Van der Grinten, 2000 cited in Peterson and Obileye, 2002). The WHO speculates that poor quality medicines may have contributed to development of resistance to cholera, salmonella, tuberculosis and other diseases (Feldschreiber, 2009). The use of counterfeit and substandard artesunate and widespread monotherapy with artesunate has led to Plasmodium falciparum artesunate resistance on the Thailand-Cambodia border (Newton et al, 2010). The recent finding of counterfeit forms of artemisinin derivative in Africa is a serious cause for concern due to fear of development of resistance to artesinin in the highly malaria endemic Africa (Newton et al, 2006a). In Ghana, 82.4% of artesunate samples which were obtained from pharmacies in Kumasi did not meet European Pharmacopoeia content requirements (Ofori-Kwakye, 2009). Counterfeit forms of Coartem™ have also been discovered in Ghana through the help of the medicine quality monitoring programme implemented by the US Agency for international development (Ghana news agency, 2009). In Kenya, several cartons of counterfeit Duo-cotexin™ and Cotexin™ containing no active ingredient were confiscated from a drug store in Nairobi (Mwaniki, 2007). Further nationwide survey of anti-malarials on Kenya revealed that about 16% of the sampled anti-malaria medicines were counterfeit (Ngiruchu, 2008). The Kenyan Medical services minister disclosed that about 80% of medicines in Kenya, majority of which are anti-malarials may be counterfeit (APA News, 2008). The director of policy and advocacy for the Confederation of Tanzania Industries (CTI) confirmed that a batch of antimalarials tested recently by the group contained only wheat flour (IRIN, 2009).

It is an obvious fact that the impact of medicines counterfeiting especially in the developing countries have been under reported because consumers may not link their non response to treatment to counterfeit drugs rather they may attribute it to other factors such as contamination of drinking water supply, disease complication, malnutrition, failure to complete the course of treatment or even a belief in curses or the supernatural (Lybecker, 2007). A study sourced from PSN, (2001) cited in Wertheimer and Norris, (2009) and Peterson and Obileye, (2002) stated that fake and substandard medicines accounted for 12.8% of adverse drug reaction, 52.9% of drug resistance, 10% of therapeutic failure, 48.2% of increased disease severity and 34.2% of the patients taking such drugs may develop complications (Peterson K and Obileye O, 2002). See table 2 below
Table 2: Fake and Substandard Drug Impacts in Nigeria

<table>
<thead>
<tr>
<th>Fake and Substandard drug impacts</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fatality rates</td>
<td>12.8</td>
</tr>
<tr>
<td>Resistance to drug therapy</td>
<td>52.9</td>
</tr>
<tr>
<td>Therapeutic failure</td>
<td>10.0</td>
</tr>
<tr>
<td>Increased severity</td>
<td>48.2</td>
</tr>
<tr>
<td>Development of complications</td>
<td>34.2</td>
</tr>
<tr>
<td>Proportion of Physicians that had life threatening encounters with fake drugs</td>
<td>29.0</td>
</tr>
<tr>
<td>Proportion of Physicians that had life threatening encounters with fake drugs, leading to death</td>
<td>9.1</td>
</tr>
<tr>
<td>Adverse drug reaction</td>
<td>23.6</td>
</tr>
<tr>
<td>Therapeutic response to adverse drug reaction when the source or brand was changed</td>
<td>29.7</td>
</tr>
<tr>
<td>Antibiotic counterfeiting accounting for total numbers of death</td>
<td>21.0</td>
</tr>
</tbody>
</table>

(Adapted from PSN, 2001 cited in (Peterson and Obileye, 2002)

Although the methods employed by the Pharmaceutical Society of Nigeria (PSN) to arrive at these estimates shown in the table are unclear, it shows that fake and substandard medicines can lead to a variety of problems.

6.0 Strategies and barriers in the fight against medicines counterfeiting; A particular focus on health professionals

There have been responses to medicines counterfeiting from government bodies, drug regulatory authorities, professional organisations and industries. Most of these responses/strategies are based on the framework on the formation of IMPACT involving key areas that were identified as needing action both nationally and internationally to tackle the problem of poor quality medicines. These five key areas are; Legislative and regulatory infrastructure, Regulatory implementation, Enforcement, Technology and Communication
(IMPACT, 2008). Similarly, the United States Food and Drug Administration (USFDA) identified 6 critical measures to combat fake drugs (Mehta, 2006);

- Securing the actual medicine and its packaging
- Securing the movement of the medicine through the distribution chain
- Enhancing regulation and enforcement
- Increasing penalties for medicines counterfeiting
- Increasing vigilance and awareness of medicines counterfeiting
- Increasing international collaboration

This section explores the roles health professionals and their organisations with particular emphasis on Africa have played in combating medicines counterfeiting and in reducing the prevalence of poor quality medicines as a whole as well as strategies employed by different countries in Africa and their regulatory bodies to curb the problem of poor quality medicines.

6.1 Response from International Organisations

The WHO addressed medicines counterfeiting internationally in 1985 at the conference of experts on the rational use of medicines in Nairobi with a recommendation that a clearing body be set up by WHO and other international organisations in order to collect data and inform governments on the extent of the problem (Amon, 2008). The WHO has collaborated with the World Health Professional Alliance (WHPA) to develop a tool kit for health professionals and patients on counterfeiting. In 1988, the WHO adopted resolution WHA41.16 requiring initiation of programmes to prevent and detect poor quality medicines (Amon, 2008). In 1992, the first international meeting on counterfeiting was held in Geneva which recommended a collaborative effort to help curb the Problem and defining a counterfeit medicine. An establishment of a network for the communication of information on counterfeit medicines was advocated (WHO, 1997). In 1994, resolution WHA 47.13 was adopted to help member states in their effort to solve the problem. In 1995, DMP-DAP project was established (assisted by Japanese government.) in pursuance of resolution
WHA47.13. This led to the organisation of a workshop in 1997 with outcomes of recommendations for international and national actions against counterfeiting, setting up of a database containing information on anecdotal reports from the literature and on reports from Drug Regulatory Authorities and Industry as well as the publication of guidelines for development of measures to combat medicines counterfeiting in 1999 (WHO, 1999a). Since then additional workshops for instance in Japan and Viet Nam, training and country studies on medicines counterfeiting for instance in Viet Nam and in Myanmar on have been carried out by the WHO. A network of 120 responsible individuals from different ministries of health was formed to inform the WHO on counterfeiting (Ham, 2003). In a bid to crack counterfeiting, WHO held a conference in Rome in 2006 which led to the Declaration of Rome and the formation of IMPACT which is aimed at forming a collaborative effort among a range of stakeholders in order to curb medicines counterfeiting. The major areas of focus of IMPACT are legislative and regulatory infrastructure, regulatory implementation, enforcement, technology development for detection of counterfeits and technology transfer to developing countries as well as communication of risk and innovations/strategies aimed at curbing counterfeiting (WHO, 2010a). The WHO in collaboration with the Pharmaceutical Institute of the University of Bonn (Germany) and the German Pharma Health Fund (GPHF) have produced a drug testing kit as a strategy against counterfeiting in developing countries (Lybecker, 2008). The IMPACT Communications working group has developed the IMPACT Communications Strategy. The group has also collaborated with Interpol to develop strategies based on the media to raise awareness of counterfeiting and has produced a variety of electronic and hard copy resource materials on counterfeiting. IMPACT in collaboration with Interpol has been conducting raids involving different countries for instance there was an operation by IMPACT/Interpol which targeted internet sites that sell counterfeit medicines in 2008 and 2009. 1200 websites involved in illicit trading were found; 153 were closed down while 12 arrests were made.

The Impact working group on regulation has revised the WHO Good Distribution Guidelines in order to make a particular emphasis on counterfeits, developed an assessment tool to evaluate national, regional, sub-regional situation and identify any gaps and needs. They have also developed guidelines for rapid response for drug regulatory authorities in cases of medicines counterfeiting.
The IMPACT working group on technology has produced a document covering technologies aimed at protecting medicines against counterfeiting, a checklist to aid authentication of suspect drugs by enforcement agencies and conducting a comparative analysis of different field testing methods based on needs of users, locations and their successes/feasibility. The working group on enforcement has its main initiatives as establishing a single point of contact, regionally and globally as well as facilitation of communication among different stakeholders. It has also produced and distributed a basic investigative tool kit manual especially for countries with little or no expertise in pharmaceutical crime, in particular counterfeiting. They have also been conducting trainings and raids in different regions in collaboration with agencies such as INTERPOL for instance are the operation ‘Mamba 1’ in East African countries (Uganda and Tanzania) in 2008 which targeted counterfeiteers of life saving medicines (Interpol, 2008b cited in Taylor and Craig, 2009). Operation ‘Mamba 11’ was conducted in 2009 and involved 3 east African countries (Tanzania, Uganda and Kenya) (Sillo, 2010). Between July and August, 2010, operation ‘Mamba 111’ was conducted and it involved 5 East African countries (Kenya, Tanzania, Uganda, Rwanda and Burundi) (Sillo, 2010). There was operation “Storm” in South East Asia from April to September, 2008, involving different countries (Cambodia, China, Laos, Myanmar, Singapore, Thailand and Vietnam) and other agencies. These resulted in closure of drug outlets, arrests and drug seizures (Interpol, 2008a cited in Taylor and Craig, 2009). Another operation coded as “Pangaea” was held from 16-20 November, 2009; coordinated by Interpol-PFIPC-IMPACT involving 25 countries such as Canada, Germany, Ireland, Israel, New Zealand, Singapore, Switzerland, the UK and the USA targeting illegal internet premises (Interpol, 2008c cited in Taylor and Craig, 2009). Interpol also coordinated operation Zambezi from 12 October, 2009 to 6th November, 2009 involving raids in four African countries; Zambia, Zimbabwe, Malawi and Swaziland (Interpol, 2009).

The working group on regulatory and legislative infrastructure developed “Principles and elements for national legislation against medical products”. It also initiated a study comparing existing legislation used to combat medicines counterfeiting. The Max Planck Institute is leading this and making comparison between different countries (WHO, 2010d). Final results of their analysis are expected in 2010 (WHO, 2010f).
Furthermore, IMPACT collaborates with other bodies such as the charity Pharmaciens sans Frontiéres, professional organisations such as the International Pharmaceutical Federation (FIP), financial institutions such as the World Bank and consumer groups such as International Alliance of Patients’ Association (Taylor and Craig, 2009). IMPACT organises conferences on drug counterfeiting and has a rapid alert system for counterfeit drugs (Newton et al, 2008). It recently held its third annual meeting in Tunisia to raise awareness of the danger of medicines counterfeiting and how best to curb it (African Union, 2010).

The WHO introduced a voluntary, confidential system of reporting medicines counterfeiting (Amon, 2008). The issue of counterfeiting was again discussed at the 63rd World Health Assembly (WHA) in May, 2010; with a resolution to create a working group on counterfeit medical products which will help to examine WHO’s role in the fight to curb counterfeiting and ensure availability of good quality medicines as well evaluate the relationship of WHO with IMPACT. The group is required to make some recommendations during the 64th WHA in 2011 (WHO, 2010c).

In addition, The WHO introduced the Certification scheme to ensure the quality of medicines and established the pre-qualification list (Weithermer, 2009). The WHO has published a lot of guidelines in the area of medicines counterfeiting (Kopp, 2010).

WHO was the first to set up the world’s web based system aimed at tracking counterfeiters in 2005; the Rapid Alert System (RAS) in the Western Pacific Region which was initiated to keep relevant authorities abreast of counterfeiting cases so that they could develop measures to counter the effects such activities could have (WHO, 2006).

The USAID and USP have launched a 5-year project (The promoting the quality of medicines program) to combat medicines counterfeiting in Africa. The United States Pharmacopoeia Drug Quality Information (USP DQI) program has also developed drug quality surveillance programs in 19 nations with one of the sites located in Ghana (Milissa McGinnis, 2010). The United Nations (UN) government agencies, the Global Fund and many international organisations that donate medicines to Africa now require that only medicines prequalified by the WHO or are approved by stringent regulatory measures are suitable for procurement (Science in Africa, 2009).
The World Customs Organisation (WCO) which is made up of 176 member customs has signed a declaration to crack down medicines counterfeiting while ensuring access to safe medicines via a global initiative (Henry J Kaiser Family Foundation International news, 2010; Kopp, 2010)

6.2 Response from different African country governments and their regulatory bodies

Nigeria

NAFDAC launched the Mobile Anti-counterfeiting Authentication Service whereby a 12-digit numerical code is sent to a free number for verification (NAFDAC, 2010b). Hewlett-Packard (HP) and Mpedigree with the support of relevant Nigerian authorities aim at introducing the Mobile Authentication Service (MAS) for malaria pills in Ghana and Nigeria by December, 2010 and may expand later to Kenya, Tanzania, Liberia, Benin and Uganda (Bennett, 2010). Kenya, Uganda and Tanzania have all expressed interest in signing up for the Mobile Authentication Service (All West Africa, 2010a). There are also plans to extend the service to other drug classes if it proves successful. This Mobile Authentication service was born out of a drive to empower consumers to authenticate the quality of their medicines. NAFDAC in collaboration with Verification Technology Ltd has launched the use of Radio Frequency Identification (RFID) solution technology to identify and verify products, documents and other important items (Ogbebo, 2010). Verayo, Skye Tech and Global PCCA are set to start supplying secure and easy to use RFID systems to Nigeria and other African countries at a relatively low cost (Taylor, 2010).

In order to mop up the fake drugs already in circulation, the Nigerian government has in collaboration with registered manufacturers, confiscated and destroyed expired AND counterfeit medicines thereby increasing the cost of obtaining such illicit medicines (Naik, 2004 in Lybecker, 2007, Akunyili, 2007). NAFDAC has engaged in raids leading to confiscation and destruction of a wide range of fake and substandard products; destroying over US$35, 753,014 worth of drugs found to be fake or substandard between 2001 and 2004 (Akunyili, 2005b cited in Milissa McGinnis, 2010). Between 2001 and 2006; drugs worth US$109 million were destroyed (Edike and Obinwanne, 2006 cited in Milissa McGinnis, 2010). The Lagos State Taskforce on counterfeitz, fake drugs and unwholesome processed

Nigeria plays an active role in IMPACT; with the Director General of NAFDAC acting as one of the chairs. Nigeria is also collaborating with medical equipment manufacturers such as Secure pharma, sproxil and Global PCCA as well as international organisations (Turkur, 2009). NAFDAC has entered into partnership with the USFDA to provide training to delegates. It aims at signing a memorandum of understanding between India and China which will help harmonise strategies employed in curbing medicines counterfeiting (Ogbebo, 2010). Nigeria also shares strategies with other countries in West African Drug Regulatory Authorities Network (WADRAN) which they supervise and sponsor. NAFDAC initiated WADRAN in 2008 as an avenue to share strategies and experiences by member states in the fight against medicines counterfeiting (Akunyili, 2007). It is made up of 12 countries in West Africa.

The Nigerian government is collaborating with the Indian and Chinese governments in the fight against medicines counterfeiting; the Chinese government has agreed to provide advanced information on drugs exported to Nigeria (Turkur, 2009). Nigeria in collaboration with Indian authorities adopted the concept of ‘whistle blower’ initiative where a cash reward of N200,000 is proposed to be given to anyone who discloses information leading to interception of fake drugs while individual identities remain confidential (This Day, 2010).

NAFDAC embarked on re-orientation and motivation of its staff for positive outcome (Akunyili, 2007). Other initiatives includes the introduction of public enlightenment campaign via jingles on the radio and television, alert notices about fake drugs in the supply chain for instance is an alert issued on fake Maloxine™ tablets in circulation in 2009 (Ogundipe and Obinna, 2009 cited in Milissa McGinnis, 2010). In addition, there are billboards and publications in national dailies on medicines counterfeiting for example; the list of counterfeited medicines and workshops/meetings/seminars for stakeholders (Akunyili, 2007). A quarterly bulletin which distinguishes between counterfeit and genuine medicines as well as original and blacklisted companies is usually published by NAFDAC (Federal
Ministry of Health and World Health Organisation, 2010). It has engaged the local governments at the grassroots by organising a workshop, letting them know the need to join the agency in the fight as well as advocacy campaigns against medicines counterfeiting (Ogbebo, 2010). NAFDAC in collaboration with Christables is starting a state to state drug market sensitization which flagged off on 15th of July, 2010 beginning with the Onitsha head bridge market, Anambra state (Daily Sun, 2010). NAFDAC has also conducted secondary school essay competition contests to help publicize the harmful effects of counterfeit drugs, established consumer safety clubs in schools, attempted to raise a NAFDAC army made up primary school children who are taught on the advantage of good quality products (Naik, 2004 in Lybecker, 2007; WIPO, 2008). To facilitate the reporting of adverse drug reactions and other drug related problems by health professionals, NAFDAC has printed Adverse Drug Reaction (ADR) reporting forms with prepaid stamps (Akunyili, 2004).

NAFDAC has been engaged in updating of NAFDAC laboratories and inspection of laboratories abroad to ensure their compliance to Current Good Manufacturing Practice (cGMP). Appointments of analysts in India, China and Egypt who re-certify drugs for importation, mandatory pre-shipment information before importation, mandatory NAFDAC clearance permit prior to financial document processing in Nigeria for all drug importers, discontinuation of importation of drugs marked ‘For export only’ into Nigeria by insisting on an authenticated certificate of free sale, regular monitoring of GMP of local manufacturers and enforcement of NAFDAC registration guidelines are also some of NAFDAC’s key strategies in eliminating medicines counterfeiting (Akunyili, 2007). It has designation Calabar and Apapa sea ports, Murtala Muhammed and Mallam Aminu Kano International Airports as the only ports of entry for the importation of drugs and pharmaceutical raw materials to avoid smuggling in illegal medicines (Wikipedia, 2010a).

Furthermore, NAFDAC has banned importation from some Indian Pharmaceutical companies, sealed some drugs from being imported (Chinyere, 2008 in Bate et al, 2010) and set up an office for its regulator in India (The Economic Times, 2009 in Bate et al, 2010). NAFDAC is conducting a survey and audit of all drugs on sale in Nigeria in order to build a pharmaceutical database (Bate and Hess, 2010). Recently, it introduced the use of thermo scientific Truscan handheld RAMAN instrument for rapid identification of fake and substandard drugs (NAFDAC, 2010a).
The Federal government submitted a draft resolution at the 63rd WHA seeking for WHO’s support in tackling its chaotic drug distribution system and enhancing the regional fight against counterfeiting (Ogudipe, 2010).

The president of the Manufacturers Association of Nigeria (MAN) has recently called for a new legislation to be implemented to reduce the importation of counterfeit, adulterated and substandard medicines in Nigeria (Securing Pharma, 2010).

**Senegal**: The government of Senegal increased its monetary budget in curbing counterfeiting in 2006 (Milissa McGinnis, 2010). USP DQI has set up medicine monitoring sentinel sites in Senegal and provided technical assistance to the National de Lutte contre le Paludisme (PNLP) in setting up a pharmacovigilance program in order to aid reporting of adverse effects of Artemisinin Combination Therapies (Hadiri, 2009). It has also provided training to members of the pharmacovigilance team on drug quality testing in order to conduct a study on the quality of antimalarials in sub-Saharan Africa (QAMSA study) (Hadiri, 2009). It supports the Drug Regulatory Authority of Senegal in the registration of medicines (USP DQI, 2009). A technical committee was created in 2009 to enforce drug regulation in Senegal as well as raise the public awareness of the impact of medicines counterfeiting (USP/USAID, 2010). A campaign “combating counterfeit medicines on the illicit market” was conducted in July, 2009 to raise the awareness of poor quality medicines sold by unlicensed vendors. A similar campaign is planned for September, 2010 (USP/ASAID, 2010).

**South Africa**: Purchasing registered medicines from licensed suppliers, use of Standard Operating Procedures (SOPs) and audits by manufacturers, distributors and health care providers were the key strategies identified that were used to protect medicines quality in South Africa (Patel et al, 2009).

**Ghana**: In 2008, the mPedigree developed a mobile drug anti-counterfeiting service in Ghana whereby consumers were required to text an 8-digit numerical code to a number for free authentication; similar system has been rolled out in Nigeria as previously described. Rwanda and Kenya are other targets for the developers of this technology (Mullard, 2010).
An Anti Illicit Trade Coalition at Kpone Landfill has been involved in the destruction of counterfeit products for instance counterfeit toothpaste (My Joy online, 2009 cited in Milissa McGinnis, 2010).

Sentinel sites for medicines monitoring were established with the support of the US government in Bolatanga, Kumasi, Ho, Accra and Tarkwa to help identify counterfeit medicines (Kwei, 2006-2009; Bate, 2010). Through this drug quality program, fake Coartem\textsuperscript{tm} has been detected in the Ghana market (U.S Pharmacopoeia press release, 2009 cited in Milissa McGinnis, 2010). Ghana, Rwanda and Kenya have introduced a system of drug distribution whereby drug shops are franchised to improve access to cheap but high quality medicines as well as high quality dispensing services. It has also helped to ensure uniform standards among drug sellers in these countries (Centre for Global Development, 2010). Diocesan pharmacies of the National Catholic Health and Pharmaceutical Services in Ghana have also established minilabs for the detection of counterfeit medicines.

**Liberia:** The Liberian medicine regulatory Authority in collaboration with USP DQI, the pharmacy board of Liberia, Ministry of health, USAID/Liberia mission and Malaria Control Program is working on how to strengthen the quality control laboratories of the ministry of health and finalising the drug legislation establishing the Liberian Regulatory Authority (Smine et al, 2009).

**Mali:** A new technology involving the use of capillary electrophoresis to detect substandard medicines was rolled out in Mali in late 2009. This technology has been used in Switzerland, USA and Japan (IRIN, 2010a). Pharmacists have led a campaign against unlicensed medicines named ‘Street drugs kill’ (IRIN, 2002). With the help of USP/USAID, training workshops on good laboratory practices have been conducted for staff members of the Official Medicine Control Laboratories (OMCLs) in Mali and Benin. Since 2008, USP/USAID through its Promoting the Quality of Medicine Programme has provided technical assistance to the OMCLs of Mali and Benin (USP/USAID, 2010)

**Lesotho:** An Intellectual Property program; OASIS (Operational Assistance, Services and Infrastructure Support) was conducted by the Police in collaboration with INTERPOL resulting in seizures of counterfeit medicines during the ‘operation fiela’ (Ilston, 2009).
**Sierra Leone:** The National Drug Safety Monitoring Programme was commissioned by the Pharmacy board to ensure drug safety in Sierra Leone (Koroma, 2006 cited in Milissa McGinnis, 2010). The Pharmacy board has been engaged in raids leading to destruction of counterfeit medicines (Massaquoi, 2007 cited in Milissa McGinnis, 2010). Its ministry of health has also increased monetary budget of the Pharmacy board so that more inspectors can be hired (Horner and Hallam, 2009 cited in Milissa McGinnis, 2010). The Pharmacy Board has deployed officials at Queen Elizabeth Quay and Lungi airport to aid inspection of medicines at its borders (Horner and Hallam, 2009).

**East Africa:** The East African Community (EAC) secretariat developed a draft policy and a bill on medicines counterfeiting. The anti-counterfeit bill was passed in Kenya and Uganda (Michael, 2010). Kenya has enacted a law on counterfeiting (Equinet, 2010). Tanzania has developed resolutions aimed at tackling medicines counterfeiting (Equinet, 2010). Malawi is in the process of enacting a law against counterfeiting which may include a 10-year prison sentence and K50million fine.

**Uganda:** The German Pharma Health Fund (GPHF) has developed a minilab for field testing of medicines in developing countries (Wertheimer and Norris, 2009). Five minilabs have been purchased to test medicines at the point of entry to Uganda (Kariuke, 2008 cited in Taylor and Craig, 2009). The Uganda National Drug Authority in collaboration with Interpol conducted raids which led to the discovery of counterfeit medicines (Ultimate media, 2009 and Wandera and Bangala, 2008 cited in Milissa McGinnis, 2010). The National Drug Authority of Uganda conducts tests on samples of medicines in Uganda in order to determine the extent of poor quality medicines (Nafula, 2008 cited in Milissa McGinnis, 2010). It also issues alerts on counterfeit medicines in circulation in Uganda (Nyakairu and Nakabugo, 2005; Bogere and Nafula, 2007 cited in Milissa McGinnis, 2010).

**Kenya:** Established a Pharmacy and Poisons Board which helps to identify and destroy counterfeit medicines as well as ensuring that pharmacies are licensed (Maina, 2008 cited in Taylor and Craig, 2009). The Pharmacy and Poisons board has launched a project in seven provinces geared towards closing down illegal drug distribution outlets (Maina, 2008 cited in Milissa McGinnis, 2010).
**Tanzania:** Its government seized large amounts of counterfeit medicines in circulation in Tanzania and have warned patients of the existence of fake Metakelfin™ and Cotexin™ tablets in its market (Rugonzibwa, 2008b and United Nations Foundation UNWIRE, 2001 cited in Milissa McGinnis, 2010). The Confederation of Tanzanian Industries (CTI) has called for an amendment in the Merchandize Act of 1963 which it deems to be outdated and ineffective in combating medicines counterfeiting (Milissa McGinnis, 2010). A key resolution by the Tanzania Food and Drug Authority (TFDA) in 2009 was to introduce the writing of trade names and batch numbers on all medicines purchased by or sold from wholesale pharmacy outlets (TFDA, 2009). TFDA carries out inspection of Pharmacies to help detect unapproved and low quality medicines (Shekighenda, 2009 cited in Milissa McGinnis, 2010). Tanzania Food and Drug Authority put a program in place for the accreditation of drug dispensing outlets and overseas the quality of services and products sold in these outlets (Centre for Global Development, 2010). Tanzania has set up more than 20 GPHF minilabs across the country (Bate, 2009)

**Angola:** The Government banned the sale of medicines as well as surgery and hospital tools in municipal markets as they were discovered not to be sold under proper hygienic conditions (Agencia Angola Press, 2009 cited in Milissa McGinnis, 2010).

**Egypt:** Warehouse raids were conducted through which a large number of counterfeit medicines were confiscated from the supply chain (CNN, Money, 2009 cited in Milissa McGinnis, 2010).

**Ethiopia:** In 2003, the Ethiopian health officials warned the public against purchasing counterfeit anti-retrovirals in the market which the Ethiopian’s Drug Administration and Control Authority confirmed did not meet necessary quality specifications (Kaisernetwork, 2003). As part of capacity building of Ethiopian’s Product Quality Assessment Directorate (PQAD), the USP/USAID through its “Promoting the Quality of Medicines (PMQ)” programme have trained 12 laboratory analysts on methods used for testing medicines quality and have collaborated with the directorate in developing Standard Operating Procedures for gas chromatography (USP,USAID, 2010).
**Zambia:** The Zambia Bureau of Standards withdraws counterfeit medicines when discovered in Zambia (Africa News, 2009 cited in Milissa McGinnis, 2010). The Zambian government issued an alert on counterfeit HIV/AIDS cure named Tetrasil™ which was later discovered to be a pesticide (Medical News Today, 2007).

**Cameroon:** Its Food and Drugs Authority exposed 30 websites in May, 2010 which are thought to be engaged in the sale of counterfeit medicines and disseminating false drug information (Kopp, 2010).

**Sudan:** The regional government of southern Sudan is utilizing the megaphone to publicise the dangers of medicines counterfeiting in its main markets. Village health committees have also been formed and holds consultations with relevant stakeholders such as the businessmen in order to help combat medicines counterfeiting in some of the counties (Sudan Tribune, 2010).

**Zimbabwe:** Police has been arresting persons involved in the dispensing of unregistered and expired medicines. The Medicines Control Authority of Zimbabwe (MCAZ) issues public alerts on other counterfeit medicines in circulation (UN Integrated Regional Information Networks, 2007 cited in Milissa McGinnis, 2010). It recently warned the public that counterfeit antiretroviral are being imported and sold in its markets and salons (Milissa McGinnis, 2010).

Police in countries such as Senegal, Mauritania and Mauritius have also been engaged in raids resulting in seizures of counterfeit medicines some of which were thought to originate from China, Nigeria, Hong Kong and Syria (Milissa McGinnis, 2010).

Leem (a body representing French pharmaceutical companies recently held a meeting in January, 2010 involving government health officials from subsaharan Africa in order to reinforce public and private efforts against medicines counterfeiting (IRIN, 2010b).
6.3 Response from Professional organisations

International Pharmaceutical Federation (FIP): It adopted the FIP/FIPMA statement “Ensuring the quality and safety of medicinal products to protect the patient” at the 1998 FIP congress. FIP policy statement on counterfeit medicines was adopted in Barcelona with a replacement of it adopted in 2003 at the FIP congress in Sidney (FIP, 2003). FIP has also been involved in creating specific and practical tools for pharmacists for fighting counterfeiting; examples include the Tools for visual inspection and Guide for Pharmacists. Several articles have been published by FIP as a means of raising awareness of the risks of counterfeiting among pharmacists and pharmacy leaders as well as educating them. Sections at FIP congress meetings in 2006, 2007, 2008 and 2010 were dedicated to discussions on medicines quality which includes counterfeiting in order to sensitize pharmacists on dangers on medicines counterfeiting (FIP, 2010b). FIP through the World Health Professions Alliance (WHPA) has been leading the IMPACT working group on communication. The WHPA tool kit (‘be aware, take action) for health professionals and public health advocates was developed in 2008 to aid detection, reporting and prevention of medicines counterfeiting (Kopp, 2010). The first ‘Be aware, take action workshop on medicines counterfeiting is scheduled for October, 2010 in San Jose, Costa Rica while a second workshop is scheduled to hold in Nigeria in November (Kopp, 2010). The WHPA (consisting of the International Council of nurses, International Pharmaceutical Federation, World Confederation for Physical Therapy, World Dental Federation and the World Medical Association) has issued a joint statement on medicines counterfeiting. FIP has also been collaborating with the Council of Europe ad hoc committee since 2004 in the fight against medicines counterfeiting. In 2008, this became the Committee of Experts on Minimizing Public Health Risks Posed by Counterfeiting Medical Products and related crimes (CD-P-PH/CMED).

Other organisation such as The International Conference of French Speaking Orders (CIOPF) has produced recommendations on the issue of medicines counterfeiting (Chauve, 2008).

International Pharmaceutical Students Federation (IPSF): The IPSF organised its first Anti-counterfeit Drug Campaign (ACDC) in 2007 with the aim of increasing the awareness of the risks posed by counterfeit medicines among students in health professions as well as providing them with the necessary information needed as to the threats of such as criminal
acts (IPSF, 2007). It has a draft document on medicines counterfeiting which is yet to be published (Chittoory, 2010).

**International Council of Nurses (ICN):** In 2005, the focus of the International Nurses’ Day (IND) was medicines counterfeiting. Its major objectives were raising the awareness of the problem, providing nurses with the tools for the detection and reporting of medicines counterfeiting as well as encouraging nurses and health professionals to lobby increased government and regulatory authorities’ attention on medicines counterfeiting (International Council of Nurses, 2005). It has also issued a position statement on tackling medicines counterfeiting (International Council of Nurses, 2005). The ICN collaborates with IFPMA in fighting fake medicines. It has also published tool kits on the extent of medicines counterfeiting and strategies in curbing it (ICN and IFPMA, 2005).

**Pharmaceutical Society of Nigeria (PSN):** The state branches of PSN organise seminars and public enlightenment campaign during pharmacy week (Erhun et al, 2001). PSN organises meetings which provide an avenue to sharing information on drug quality in order to guide importers (Orivri, 2009). The Kano chapter sealed 5 drug company depots after concerns were raised that the companies were engaged in the manufacture of substandard medicines (Muhammad, 2009 cited in Milissa McGinnis, 2010). It has also organised workshops and seminars on medicines counterfeiting and drug quality in Nigeria (Ogbebo, 2010). The Association of Community Pharmacists of Nigeria (ACPN) which is part of the PSN has been engaged in the destruction of fake and expired drugs (Ogbebo, 2010).

**National Medical Association of Nigeria:** It organises a monthly Continuing education programme where doctors are taught on drugs/drug quality. It also collaborates with NAFDAC from which it obtains the list of banned pharmaceuticals which it disseminates to its members (Orivri, 2009).

**Medical experts in Uganda** collaborates with the Police to conduct raids in order to confiscate poor quality medicines (The New Vision, 2008 cited in Milissa McGinnis, 2010).
6.4 Barriers

Due to the nature of counterfeiting, it is almost impossible to evaluate the effectiveness of different anti-counterfeiting strategies. This is because as techniques aimed at combating medicines counterfeiting are developed, the purveyors of these illicit products increasingly become sophisticated. An economic model was developed by Currais et al. (2008) to determine the impact of differential in perceived quality and cost of genuine and fake drugs on the prevalence of medicines counterfeiting. The model revealed that the efficacy of policies and strategies adopted in the fight against this illicit crime is highly dependent on the level of impact on both differential perception of quality as well as cost differential. In most cases such strategies are influenced by the conflict of interests between different stakeholders (Currais et al, 2008). The economic model showed that some strategies such as those that are geared towards increasing penalties for offenders and those that increase cost of counterfeiting such as development of anti-counterfeit technologies or those that help to secure the supply chain have greater effect on tackling counterfeiting when compared with campaigns that raise consumer awareness of the dangers of counterfeit medicines such as the use of high school essay competitions to publicize the dangers of counterfeiting as it is done in Nigeria (Lybecker, 2007). Except for campaigns that help consumers to distinguish between fake and genuine pharmaceuticals which may be beneficial, strategies or campaigns that raise awareness of consumers of dangers of counterfeiting may result in fall in the sale of medicines as well as increase in counterfeiting which consequently leads to lack of access to good quality medicines (Lybecker, 2007). An evaluation of a public awareness campaign on the dangers of medicines counterfeiting in Cotonou, Benin showed that it was effective in increasing awareness. About 90% understood the dangers of illicit medicines leading to a reduction in their demand for such drugs (Abdoulaye et al, 2006a). However, the findings of this evaluation study may not be conclusive as other factors may have contributed in the change in the consumer behaviour. Recently, a mobile anti-counterfeiting authentication service (MAS) was introduced in Nigeria in collaboration with Sproxil Inc.; requiring consumers to send a unique code located on the scratch card on the package of their medicines to a short code to authenticate their medicines (Health Care Packaging, 2010). Small trials of the Mobile Authentication Service have been conducted in Ghana, Kenya, Rwanda and Nigeria (All West Africa, 2010a). In Nigeria, a 100-day pilot project aimed at determining the feasibility and cost implementation of the mobile anti-counterfeiting
authentication service showed that some customers are utilising the service and are at no cost to the patient (Sproxil, 2010). However, it may be too early to ascertain if such services may not indirectly lead to increases in medicines cost. There are anecdotal reports suggesting that the counterfeiters are already co-selling genuine medicines containing the unique identification code with the counterfeit versions in a bid to deceive the customers (Chu, 2010). Also questions of whether on expansion, all legitimate manufacturers of medicines distributed in Nigeria can be included in the program or if smaller firms producing locally-made versions or legitimate generics available who may not be able to afford it be excluded from the programme (Freschi, 2010). If the later is true, it may mean that these smaller firms manufacturing medicines affordable to the Nigerian population may be driven out of business by the larger firms and in turn lead to decreased access to some life saving medicines (Freschi, 2010). Although the perceived cost involved in trying to replicate MAS by the counterfeiters may discourage them from further counterfeiting (New York, 2010), it is important that serious consideration is given to medicines and firms who would be engaged in this initiative upon expansion and that the Federal Government of Nigeria is prepared not to forsake the public health implications of access to good quality affordable medicines at the expense of promoting the authentication of genuine drugs from larger multinational manufacturers.

One of the barriers in the fight against medicines counterfeiting is the conflict of interest which may exist between government agencies who are motivated by the public health burden associated with poor quality drug use and the industries which may be motivated by profit and issues of intellectual property theft rather than the potential harm caused by such medicines to patients. Globalisation, increase in world trade, advances in desktop publishing as well as advancement in production technologies are just some of the factors that has helped the proliferation of medicines counterfeiting as counterfeiters can even purchase their packaging from the same companies as the genuine manufacturers (Lybecker, 2007 and Schofeild, 2001).

Furthermore, the introduction of such strategies as the use of pedigrees systems (a drug’s pedigree contains its complete history of its custody from the manufacturer to the point when it is dispensed (Verisign, 2005) is faced with a consequent increase in the volume of additional work even in America where drugs are transported in bulk and an increased cost
for the wholesalers and other traders (Taylor and Davies, 2008). It has been argued that the use of advanced safety measures will hardly be maintained through the supply chain if such activities as parallel trading continue since they may have to be removed or replaced by re-packagers (Taylor and Davies, 2008). An option seems to be to adopt a two-tier system where drugs that may most probably be counterfeited are protected with safety measures while other less valued medicines will not. However, this practise has been criticised as all medicines may be counterfeited including the less valued products whose economies of scale may make them attractive to the counterfeiters (Taylor and Davies, 2008 and Kaur et al, 2010).

A possible barrier to anti-counterfeiting efforts is the increased valuation of high quality medicines for instance through advertisement by the pharmaceutical industries; thereby increasing demand of such highly advertised products and consequently making such products an ideal target for counterfeiters. A typical example is Viagra™ which is frequently targeted for counterfeiting due to increased demand for it. However, other factors may actually be responsible such as the tendency of consumers to purchase drugs for sexual dysfunction from unscrupulous channels rather than the legal distribution chain (Lybecker, 2007). Also, there may be some difficulty in making firms not to advertise their product in order to avoid counterfeiters from targeting it. Among other barriers noted by Lybecker, (2008) is the fact that technologies involving the use of simple testing kits to detect fake medicines may be limited as they may only be able to identify some few ingredients.

Definitional confusions in this area also contribute a serious barrier to the fight against the crime for instance, while NAFDAC considers medicines not registered by it as counterfeit, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) warns that medicines authorised for marketing by one regulatory authority but not by another should not be deemed counterfeit in the territory of the later (IFPMA, 2010).

Simple and affordable field techniques currently used for rapid screening of drug quality in resource poor countries such as Nigeria have been flawed by various limitations; for instance minilab kits were found to detect only grossly substandard or counterfeited medicines after a pilot study was conducted by the Tanzanian Food and Drugs Authority (Kaur, 2010). Hence, the recommendation that minilab be used in conjunction with medicine quality control laboratories (MQCL) (Risha et al, 2008 cited in Kaur, 2010). Also, the use of other
techniques for detection of drug quality such as the use of HPLC have been found to be expensive and requiring a considerable amount of expertise. Although liquid chromatography-mass spectrometry (LC-MS) reveals an enormous amount of chemical information, it is relatively tedious and involves a time consuming sample preparation. In order to overcome this challenge, the use of open air ionisation techniques, direct analysis in real time (DART) and Desorption electro spray ionisation (DESI) which are less time consuming have been developed (Kaur, 2010). Some field tests for combination drugs such as antimalarials that rely on colour tests may be fooled by the counterfeiters; for instance one of the tests for artemisinin is dependent on its yellow colour but at least 2 antimalarials available are yellow and may give a false result according to Harparkash Kaur (Willyard, 2010). The presence of small quantities of artesunate in samples may give false positive result to the Rapid Red dye test (Newton et al, 2006b). Bioavailability studies via dissolution tests are also expensive to carry out due to their sophisticated nature. Due to the destructive nature of methods based on colorimetry, refractometry and chromatography, non-destructive spectroscopic methods such as Raman and near infrared spectroscopy are currently been evaluated for use (Kaur, 2010). The use of hand held Raman spectrometers such as the Truscans purchased by NAFDAC is extremely useful, however it is not left with disadvantages as they are subject to interference from inactive components of the pill according to (Mullard, 2010). Also, the Raman spectroscopy may not be able to accurately detect content uniformity of the product tested since only the surface of the sample is usually detected unlike the infrared spectroscopy which penetrates through the sample surface, hence may not detect any non-uniformity of ingredients (Kaur, 2010). Both techniques (Raman and Infra red) require fingerprinting to match the spectra of the tested sample with those on the database. However Raman spectroscopy just like NIR requires less training unlike the use TLC. This may make it compare favourably with TLC even in terms of cost as the cost of staff training is not incurred (Bate et al, 2009b). Raman spectroscopy provides both quantitative and qualitative information, not invasive and is less susceptible to external interference and climate change unlike NIR (Near Infrared) and TLC (Thin Layer Chromatography (Bate et al, 2009b). Track and trace technologies such as RFID (Radio Frequency Identification) are less reliable with relatively high error rates and costly especially when it is used on individual products rather than on batches and when it is compared with the use of 2D-Encryption which has been found to be less expensive (Hemalatha, 2008). The use of simple digital camera and free downloadable software is
currently under investigation for use in determination of content of active ingredient (Fernandez et al, 2008).

The legislation in most countries has been shown to be inadequate in a survey currently performed on 50 most populous nations (Anisfeld, 2007). The survey revealed that only 16 of the 50 countries have legislation with particular reference to medicines counterfeiting; most of which are outdated. Drug counterfeiting is regarded as an Intellectual (IP) matter in most countries rather than seen from a public health point of view and the punishment for drug counterfeiting is not always different from counterfeiting of other goods such as handbags and may even be less severe in some cases (Anisfeld, 2007). Inadequate number of inspectors, low salaries of inspectors which are linked to increased bribery and corruption rate, insufficient funding for laboratories and inadequate international collaboration are barriers to enforcement of the existing legislation in most of the countries (Anisfeld, 2007).

Other barriers to fighting counterfeiting remains the nature of legal systems in most countries such as the slow litigation processes which encourages the criminals to carry on with counterfeiting since many of the cases may never really be concluded (Bate et al, 2010). In addition to this, is corruption which is rife in many countries that have a major problem with counterfeiting with many cases of counterfeiting linked to top government officials. Bate et al, (2010) cites instances of such in African countries such as Uganda and Nigeria (Yar, 2008).

Finally, there are currently agitations from groups such as Health Action International and Equinet amongst others that the definition adopted for counterfeit medicines especially as included in the Ugandan bill and Kenyan law may be too broad to include generic medicines and so may impede access to the more affordable generic medicines which majority of the people in developing countries depend on (Equinet, 2010). There are also concerns that the WHO actions via IMPACT are geared towards IP protection thereby compromising its public health role as raised at the 63rd World Health Assembly. Sequel to the concerns and other discussions from the 63rd WHA, the WHO decided to create a working group to evaluate the concerns and proposals raised by the member states as well as advocating that the Director General of WHO held consultations with member states and regional economic integration organisations on specific issues WHO, 2010e). The working group is expected to report its recommendations via the executive board at the 64th WHA (WHO, 2010e). These conflicts
and controversies have been a major impediment to any progress made so far towards curbing medicines counterfeiting.

7.0 Conclusion

Medicines counterfeiting in less developed countries has previously been ignored due to perceived low profitability of such markets, the supposedly unique nature of the “ethical” drugs market and fears of loss of reputation. However, with advances in technology and globalisation, it is rightly beginning to attract increased attention (Lybecker, 2008).

Government of different countries in Africa as well as health professional organisations have to a relatively small extent responded to the problem. However, there is still a long way to go in ensuring a zero tolerance to this illicit crime. There is need for all stakeholders involved in this fight against counterfeiting to continually be a step ahead of the counterfeiters in order to make any significant influence. Effective coordination and cooperation at the international level is required for regional and national strategies to be more effective (Reggi, 2007). In tackling this problem, it must be born in mind that for some, counterfeit medicines are the only treatment option despite any fatal risks associated with them. Perhaps, a good starting point may include addressing the global patterns of exclusion from health care and ensuring an equitable access to legitimate and safer alternatives which are affordable (Yar, 2008).

Health professionals are in a good position to help fight medicines counterfeiting through their advanced role in the detection and reporting of counterfeited products and in empowering the consumers with the knowledge needed to avoid counterfeit medicines. They also have a role to play in developing national systems which will be useful for collection of information regarding medicines counterfeiting as well as supporting the national drug regulatory capacity to aid pharmaceutical guideline enforcement (WHPA, 2010). They can work with medicine manufacturers to learn about quality products and ways of detecting counterfeits as well as provide continuing education programmes on the detection and reporting of counterfeits (World Health Organisation, 2003). Inter professional relationships is needed so that health professionals can begin to tap from each other’s core competencies in fighting this menace (Akunyili, 2004). There is also a need for health professional organisations in all African countries to begin to document their activities which are aimed at curbing medicines counterfeiting as the dearth of information from the majority of the
countries point to the fact that there may be significant under reporting or that nothing is been
done to counter medicines counterfeiting in these countries.
Abbreviations

ACPN: Association of Community Pharmacists of Nigeria
ACT: Artemisinin Combination Therapy
ACTA: Anti-Counterfeiting Trade Agreement
ADR: Adverse Drug Reaction
AFRO: African Regional Office
AIPM: Association of International Pharmaceutical Manufacturers
AMRO: American Regional Office
ASEAN: Association of Southeast Asian Nations
ASHP: American Society of Health System Pharmacists
BBC: British Broadcasting Co-operation
BP: British Pharmacopoeia
CD-P-PH/CMED: Experts on Minimizing Public Health Risks Posed by Counterfeiting Medical Products and related crimes

cGMP: Current Good Manufacturing Practice; GMP: Good Manufacturing Practice
CIOPF: Conférence Internationale des Ordres de Pharmaciens Francophones
CTI: The Confederation of Tanzanian Industries
CWPA: Common Wealth Pharmacists Association
DEG: Diethylene glycol
DRA: Drug Regulatory Agency
EAC: East African Community
EDQM: European Directorate for Quality of Medicines and Health Care
EFPIA: European Federation of Pharmaceutical Industries and Associations
EMEA: European Medicines Agency
EMRO: East Mediterranean Regional Office (Majority of the Middle East countries and Pakistan)
EURO: European Regional Office
FIP: International Pharmaceutical Federation
GMP: Good Manufacturing Practice
GPHF: German Pharma Health Fund
ICN: International Council of Nurses
IFPMA: International Federation of Pharmaceutical Manufacturers and Associations
IMPACT: International Medical Products Anti-counterfeiting Taskforce
INTERPOL: International Criminal Police Organization
IP: Intellectual Property
IPSF: International Pharmaceutical Students’ Federation
IV: Intravenous
LMHRA: Liberia Medicines and Health Products Regulatory Agency
MAN: Manufacturers Association of Nigeria
MCAZ: Medicines Control Authority of Zimbabwe
MDRTB: Multi Drug Resistant Tuberculosis
MHRA: Medicines and Health Care Regulatory Agency.
NABP: National Association of Boards of Pharmacy
NACDS: The National Association of Chain Stores
NAFDAC: National Agency for Food and Drug Administration and Control
NIR: Near Infrared
NMA: National Medical Association
NABP: National Association of Boards of Pharmacy
OASIS: Operational Assistance, Services and Infrastructure Support
OECD: Organization for Economic Cooperation and Development

OMCLs: Official Medicine Control Laboratories

PCN: Pharmaceutical Council of Nigeria

PDMA: Prescription Drug Marketing Act

PFIPC: Permanent Forum for International Pharmaceutical Crime

PGM-MAN: Pharmaceutical Group of Manufacturers-Manufacturers Association on Nigeria

PhRMA: Pharmaceutical Research and Manufacturer’s Association

PMQ: Promoting the Quality of Medicines

PMV: Patent Medicine Vendors

PNLP: National de Lutte contre le Paludisme

PSI: Pharmaceutical Security Institute

PSN: Pharmaceutical Society of Nigeria

RAS: Rapid Alert System

RFID: Radio-frequency Identification

RPSGB: Royal Pharmaceutical Society of Great Britain

R & D: Research and Development

SEARO: South East Asian Regional Office (Includes India)

SFDA: State Food and Drug Administration

SOPs: Standard Operating Procedures

SPOC: Single Point of Contact

TB: Tuberculosis

TFDA: Tanzania Food and Drug Authority

TLC: Thin Layer Chromatography

UMI: Unique Medicine Identifier
USAID: United States Agency for International Development

USFDA: United States Food and Drug Administration

USP: United States Pharmacopoeia

USP DQI: United States Pharmacopoeia Drug Quality and Information Program

UV: Ultraviolet

WADRAN: West African Drug Regulatory Authorities Network

WCO: World Customs Organisation

WHA: World Health Assembly

WHO: World Health Organisation

WHPA: World Health Professional Alliance

WIPO: World Intellectual Property Organisation

WPRO: West Pacific Regional Office (Austria, China, Vietnam and Philippines)

WTO: World Trade Organisation
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