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DISCUSSION PAPER ON COUNTERFEIT AND SUBSTANDARD MEDICINES

Advocacy and Policy Committee Members

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1.0 Background and Overview of the Pharmaceutical Sector

In 1999, MOH developed and adopted a National Drug Policy (NDP), which is based on the requirements of the Basic Health Care Package (BCHP).A three year procurement plan for the period 2005 to 2007 was developed and the "Essential Drugs" and "Tracer" Drugs lists were also developed, intended to help in monitoring stocks and management of procurements for critical drugs and supplies. Over the past years, the bulk supply of essential drugs and medicines supplies was erratic with more than 50% of essential drugs out of stock.However; the availability of Rural Health Centers Kits (RHCK) was fairy steady. On average, Health centre stocks improved from 73% in 2002 to 76% in 2004.Currently, the health sector in Zambia is experiencing a human resource crisis, which is significantly undermining its capacity to provide even the basic health care services to the people. The pharmaceutical sector is worst hit.However, the government is determined to reverse this trend as envisioned in the National Drug Policy and the Pharmaceutical Act(No.14) of 2004.The training of Zambian pharmacists was mostly done outside the country until 2003 when the programme to train pharmacists at the Medical School was established in line with the NDP recommendations. Now Zambia produces on average 35 pharmacists per which is a big milestone. The Zambian Government has also established the Pharmaceutical Regulatory Authority in line with the NDP recommendations to strengthen medicines control in the country.

When patients receive a counterfeit medicine, they are subjected to multiple risks. They often suffer more than just an inconvenience; as they become victims of fraud medicines and are all put at risk of adverse effects from unprescribed medicines or substandard ingredients. Additionally, patients may lose confidence in health care professionals including their physician and pharmacist, and potentially modern medicine or the pharmaceutical industry in general. Counterfeit or substandard (poor quality) drugs pose threats to society; not only to the individual in terms of the health side effects experienced, but also to the public in terms of trade relations, economic implications, and the effects on global pandemics. It is vital for suppliers, providers, and patients to be aware of current trends in counterfeiting in order to best prepare for encounters with suspicious products. Furthermore, this is an issue that needs to be continually dealt with on national and international policy levels. Developing countries should try their level best to establish good laboratories for monitoring and checking quality of all pharmaceuticals manufactured locally and those imported or donated to these countries. The Ministries of Health and all stakeholders

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involved in this issue must ensure that all drugs meet the set or established international standards and national standards. Failure to do so will be to misuse the hard earned forex that is normally borrowed from banks for the procurement and distribution of drugs to its people. Indeed sub-standard medications do more harm than good to people's health and it is unethical to give such drugs to people. Of course, in any market, some corruption and fraud always exist, but there are few commercial markets where fraud can have such drastic impact on global health and welfare. It is essential, therefore, that a multi-faceted approach be used to control this problem which affects the international community and continuously threatens the health of millions of people especially in developing countries.

Country Pharmaceutical Profile

COUNTRY SNAPSHOT	Zambia	AFRO
Total Population	11,696	-
Life expectancy at birth	40-40	47-49
Per capita health expenditure US $	21	
Per capita government expenditure on health US $	11	
Per capita government medicines' budget US $	2	
Number of registered pharmacists	251	
Pharmacists for 1,000 population	0.10	0.06
Median availability of key essential medicines at public health facilities	86%	-
National Medicines Policy(last update)	n.a	-

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Essential Medicines list(last update0	2007	-

2.0 Definitions Counterfeits and Sub standards

What are Counterfeits?

A counterfeit is an imitation that is made usually with the intent to deceptively represent its content or origins. Although most frequently used to describe forged currency or documents, the word ‘’counterfeit’ also describes the fraudulent imitation of a variety of consumer goods, particularly those which are very expensive or desirable, or those which are cheap and easy to reproduce. Counterfeit attempt to deceive consumers into thinking they are purchasing a legitimate item, or convince that they could deceive others with the imitation.

Any kind of product can be (and probably has been) counterfeited, including medicines here in Zambia.

Counterfeited medicines with the appropriate active ingredients in subclinical amounts can also lead to prolonged illness or death, but pose the further risk of encouraging the spread of drug resistant pathogens. Although much counterfeit medicine trade occurs in the unregulated market, especially in developing countries, counterfeit medicines are also found extensively in licensed pharmacies.

WHO defines a counterfeit medicines *as ‘’a medicine that is deliberately and fraudulently mislabeled with respect to identity and /or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.’’*

According to the WHO definition, what makes a medicine counterfeit is the deliberate or intentional (criminal) nature of the mislabeling of a product.

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Counterfeit medicines represent an enormous public health challenge: they cause harm to patients and sometimes lead to death. Counterfeit medicines are found everywhere in the world. They range from random mixtures of harmful toxic substances to inactive, ineffective preparations. Some contain a declared, active ingredient and look so similar to the genuine product that they deceive health professionals as well as patients. But in every case, the source of a counterfeit medicine is unknown and its content unreliable. Counterfeit medicines are always illegal. They can result in treatment failure or even death. Eliminating them is a considerable public health challenge

Zambian definition of Counterfeit under the Pharmaceutical Act. NO 14, 2004

33. (1) A person shall not manufacture, import, export, distribute or sell substandard, counterfeit or adulterated medicines or allied substances.

(2) A person who contravenes subsection (1) commits an offence and shall be liable, upon conviction, to a fine of not less than three hundred thousand penalty units but not exceeding five hundred thousand penalty units or to imprisonment for a term of not less than five years but not exceeding ten years, or to both.

Comment: This particular provision in the pharmaceutical Act does not explain what a substandard drug is as well as what constitutes a counterfeit.

The term counterfeit medical product describes a product with a false representation of its identity and or source. This applies to the product, its container or other packaging or labeling information. Counterfeiting can apply to both branded and generic products.

Counterfeits may include products with correct ingredients/components, with wrong ingredients/components, without active ingredients, with incorrect amounts of active ingredients, or with fake packaging.

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Violations or disputes concerning patents must not be confused with counterfeiting of medical products. Medical products (whether generic or branded) that are not authorized for marketing in a given country but authorized elsewhere are not considered counterfeit.

Substandard batches of, or quality defects or non-compliance with Good Manufacturing Practices/Good Distribution Practices (GMP/GDP) in legitimate medical products must not be confused with counterfeiting.

It is believed that the internet is widely contributing to the spread of counterfeit medicines, as a huge number of medicines enter the market through the internet as compared to those that are brought to the market through the legal channel of distribution.

Statistics world wide show that counterfeiting is greatest in regions where regulatory and enforcement systems for medicines are weakest and this includes many African countries and in parts of Asia, Latin America, and countries in transition.

Countries that have effective regulatory systems and market control i.e. Canada, New Zealand, Austrialia Japan, most of the European Union and the United States of America. The incidence rate of counterfeits is extremely low.

Medicines of all kinds have been counterfeited whether branded or generic and these range from medicines for the treatment of life-threatening conditions to inexpensive versions of painkillers and antihistamines.

Counterfeit medicines are illegal and they can result in treatment failure or even death.

What are substandard Medicines?

Substandard medicines are genuine medicines produced by manufacturers and they do not meet the quality specifications set for them by national standards.

Normally, each medicine that a manufacturer produces has to comply with the quality standards and specifications. These are reviewed and assessed by the medicines regulatory authority before the product is authorized for marketing.

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Substandard medicines arise mostly due to the application of poor manufacturing practices by the producer or when a good quality medicine is stored and distributed under improper conditions leading to deterioration of the quality of the product.

It should be noted that there is a possibility for a substandard medicine to be considered a counterfeit, this could happen if a legitimate manufacture gets involved in a criminal activity and produces a substandard product intentionally or deliberately. After all, what makes a product counterfeit is the criminal act involved.

It should be noted that there are no good quality counterfeit medicines. It is true that, sometimes, a counterfeit medicine may pass laboratory tests but this does not mean that it is of good quality. Good Manufacturing Practices require that the label should indicate, among others, the name of the active ingredient, the name of the manufacture and the country of manufacture. If a manufacture intentionally hides or gives wrong information regarding any of these products become counterfeit. Counterfeiters should not be expected to produce good quality since their motive is to make money unlawfully.

Counterfeits have been reported to occur worldwide. The problem of counterfeits is not limited to developing countries alone. They are also found in developing countries where regulation is ineffective, smuggling is rampant and sanctions are absent or very weak, and there is high corruption.

Producing counterfeits medicines may not require building huge infrastructure or facilities. they can be produced in small ‘’cottage’’ industries, or in backyards or even under the shade of a tree; For a counterfeiter, ingredients costs can be very low if cheap substitutes are used or omitted altogether as is often the case. There are also no overhead costs due to costs of quality assurance or meeting Good Manufacturing Practices (GMP) standards since such standards are never implemented; a counterfeit has better capacity to deceive particularly if it is copied to make it look like the original product. Patients and/or purchasers are not able to detect whether the product they are buying is of good quality let alone to detect whether the product is a counterfeit.

3.0 The Zambian Scenario

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What encourages counterfeiting in Zambia

- Lack of political will and commitment to establish strong national medicines regulatory authorities.
- Lack of appropriate medicine legislation
- Absence of or weak national medicines regulatory authorities
- Weak enforcement.
- Corruption and conflict of interest.
- Shortage or erratic supply of medicines
- Inappropriate use of medicines
- High prices of medicines
- Price differentials
- Inefficient co-operation between stakeholders
- Lack of control over export medicines
- Trade through several intermediaries
- Trade through free-trade zones/free ports.

4.0 Examples of Counterfeit Legislation in other Countries

In order to mitigate the problem of counterfeits on the market countries in Africa such as Kenya and Uganda have gone further in coming up with Anti-Counterfeit Legislation. It is important that a number of developing countries that are affected by counterfeits should learn from the experiences of the aforementioned countries.

Below is an overview of Kenya and Uganda's experience in coming with anti-counterfeit legislation in the pharmaceutical industry as well as that of trade and commerce.

Confusion of Anti-Counterfeit legislation in Kenya

The immediate concern is Kenya's anti-counterfeit Act 2008 which came into effect in July 2009.This law is yet to be challenged.

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This Act defines ‘’Counterfeit’’ as;

Taking the following actions without the authority of the owner of any intellectual property right subsisting in Kenya or else where in respect of protected goods.

(a)The manufacture,production,packaging,re-packaging,labeling or making, whether in Kenya or elsewhere, of goods whereby those protected goods are imitated in such manner and to such a degree that those other goods are identical or sustaintantially copies of the protected goods;

(b)The manufacture, production or making, whether in Kenya or else where, the subject matter of that intellectual property, or a colorable imitation thereof so that the other goods are calculated to be confused with or to be taken as being the protected goods of the said owner or any goods manufactured, produced or made under his silence;

(c)The manufacturing, producing or making of copies, in Kenya or elsewhere of an author’s rights or related rights.

In this Act ‘’ counterfeit goods’’ means goods that are the result of counterfeiting, and included any means used for purposes of counterfeiting.

It is believed that this Act violates the right to life and health in Kenya, In that it makes access to affordable life-saving generic medicines and therefore robs them off their right to life;
The issue is of life-and-death importance as generics, which are between 70 and 90 percent cheaper than their brand-name counterparts, have enabled poor people in developing countries to get the necessary treatment.

International donors that fund drug distribution, including the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR) and the Global Fund to Fight AIDS, Tuberculosis and Malaria, also source from generics manufacturers.

It has been pointed out that the Anti-Counterfeiting Act of 2008 contains ambiguities which could

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lead to misinterpretation, undermining the government's efforts to ensure access to essential medicines for all Kenyans.

It has also been known that the act, which is aimed at cracking down on fake batteries, pens, drugs and cosmetics, "contains a vague definition of counterfeiting which could be read to include generic drugs". Generic medicines are described as legitimate, effective and exact copies of brand-name products.

The law makes the manufacturing, importation or sale of "counterfeit goods" a criminal offence rather than a civil matter, which is the usual way in which disputes over intellectual property rights, are resolved.

The onus to verify whether goods are fakes or not has been put on customs officials and police officers.
"The law further gives these officials excessive powers, making the process difficult and expensive. Moreover, the onus to prove that the product is not fake lies with the accused, a price many will not be willing to pay."

Activists argue that the existing Pharmacy and Poisons Board should be in charge of combating counterfeit medicines as it has the necessary technical expertise to deal with such issues – which customs officials don't. The latter could "imagine" something is counterfeit and cost the lives of many.
The risk is simply too high and will potentially keep away generics manufacturers and importers. This is also because the cost of the whole process, should the products be confused for counterfeits, will be too high.

The Kenyan law seems to be serving as a template for similar policies at regional level in East Africa and in neighboring Uganda.

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"Parliament in Kenya was under immense pressure to pass this Act without taking into account a number of key concerns that arise as to passing such law.

Confusion over counterfeit legislation in Uganda

The Ugandan government is considering amendments to a proposed anti-counterfeit law that after pressure from public health activist and its own pharmaceutical industry which says that the law could hamper access to affordable medicines in the country.

The push to enact the anti-counterfeit goods bill could undermine the progress Uganda has made in the fight against HIV/AIDS and ultimately hamper trade by limiting access to generic medicine and other products on the Ugandan market.

The bill defines "counterfeit goods" as goods that are an imitation of something else with an intent to deceive, and includes any device used for the purposes of counterfeiting and goods which breach intellectual property rights and goods intended to gain unfair commercial advantage with goods of a similar nature"

This definition is so broad that it could allow pharmaceutical companies to charge legitimately produced generics as counterfeits even if its patent is not registered here, which is against the principle of territorial application of Intellectual Property Rights.

In East Africa, Uganda will be second to Kenya to enact such legislation although it's worth noting that in Kenya three individuals have filed a constitutional petition contending that the newly enacted Anti-Counterfeit Act threatens their access to generic medicines and risks their human right to life as enshrined in the Kenya Constitution.

Further, Generics are products not associated with a private or national brand name; they can only be identified by their category. This implies that generics are not counterfeits because they are not pretending to be a known brand. Because generics are cheaper than national brand products, it is probable that under the bill such products will be deemed to be intended to gain unfair commercial

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advantage with goods of a similar nature and hence denied access to the stream of commerce as counterfeits.

These kinds of barriers do not exist even in developed countries. In the USA, there are big pharmaceutical companies such as Walgreens, CVS and Duane Reade that make products that are equivalent or better than national brand products, and yet cheaper. On access to affordable medicines, anti-counterfeit legislations are being misused to take away countries' rights to access more affordable generic medicines - medicines that save lives and help lower costs.

There is already an outcry all over Africa that the growing push to enact anti-counterfeit laws could undermine access to affordable medicines. At least 17 shipments of legitimate generic medicines, including ARVs, have been seized in Europe because of counterfeit legislations, which put treatment programmes at risk. In one instance, Dutch Customs officials seized a consignment of generic ARVs destined for Nigeria and purchased by the Clinton Foundation through UNITAID, claiming they were counterfeits.

Such misplaced enforcement not only hampers access to essential medicines for those in need but also frustrates legitimate trade in generics. Competition between originator and generic medicines has substantially decreased the cost of medicines and other products, which needs to be appreciated by governments and other stakeholders as an essential prerequisite to the attainment of a healthy and dignified life of people.

Resolution 141 of 2008 of the African Commission on Human and Peoples' Rights provides a yardstick to any anti-counterfeit legislation. The resolution signed at the 44th ordinary session held in Abuja, Nigeria, in November 2008, creates a link between access to affordable medicines and the right to a healthy and dignified life.

It gives emphasis to the fact that access to medicines forms an indispensable part of the right to the highest attainable standard of health and stresses that the right to health mandates each state to promote the realization of the right to medicines for all.

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Access to generics is being frustrated under the pretext of fighting counterfeits and as a result, the lives of many African people are at risk. If this is not checked, especially in Uganda, the success registered in the fight against HIV/AIDS could be reversed.

Counterfeit drugs are a serious concern for developing countries, but clear and applicable legislation will reduce their prevalence. However, should Uganda and Kenya fail to include generic drugs in the legal category or not define the sub-sector's status, drug procurement processes in the country could be negatively affected, as the government will be forced to purchase only patented medicines, which are more expensive.. This will indirectly perpetuate the demand for cheaper alternatives, making counterfeiting a lucrative though illegal business.

The negative implications for Ugandan drug makers that want to export to Kenya and Tanzania cannot be overlooked. However, should strict regulations be imposed on Indian-derived pharmaceuticals, local drug production will be further encouraged, although another caveat is that a sizeable number of domestic pharmaceutical firms are joint ventures with Indian investors.

The failure to discriminate between generic and counterfeit medicines has the potential to damage Uganda and Kenya's -Indian pharmaceutical industry relations. We expect Indian firms in co-partnership drug makers to rapidly respond to any planned policies that could damage trade. Although any changes will specifically affect imported generic drugs, variable interpretations of the law could prove equally unfavorable to domestic production.

Importantly, too hasty a revision to current laws, with the aim of being perceived to be addressing counterfeiting issues, could indirectly exclude cheaper generics from the market and limit access to medicines.

5.0 Evidence Supporting Recommendations

- In general, availability of all classes of medical products in Zambia improved following the liberalization of the economy, specifically after 1991.

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- However, this improvement is nullified by the high cost of medicines from the private sector outlets, and also by the poor financing, erratic procurement and poor distribution of essential commodities in the public sector and weak regulatory mechanisms.
- Retail prices of pharmaceutical products appear to be set by the market with some degree of regulation.
- There are 'successes' in the public sector, namely at Faith-based organizations.
- However,commercially,the focus for the few retail pharmacies, is on the high value branded products, or high turnover, the low value core products such as pain- killers ,etc
- The concentration of retail pharmacies remains in the few major cities (Lusaka, Kitwe, Ndola and Livingstone; that is along the 'line of rail' from Livingstone in the Southern Province, to the Copperbelt towns north of Lusaka).
- Most of the districts have no commercial pharmacies.
- Due to a serious shortage in pharmacists (in fact this phenomenon appears to be common in the region), specifically those in retail practice, the number of commercial outlets is further reduced, and this more so at the district level.
- The common source thus becomes either the Ministry of Health clinics or hospitals, or Faith -based organization, or the few commercial or fee paying private hospitals and clinics, or the few NGO health facilities or unlicensed outlets.
- Availability of essential drugs and medical supplies in the public sector depends on firm procurement and practices which are further based on firm planning, assured financing of goods and services, firm commitments to pharmaceutical and medical supplies in form of procurement contracts.
- Where the above is uncertain or erratic, confidence is absent from all stakeholders, specifically industry, resulting in abnormal prices and terms of conditions.
- As a result 'access' to essential drugs is critically reduced.
- The 'success' at Faith-based medical centers probably results in high patient attendance levels due to the perceived reliability in availability of drugs and medical supplies, leading to higher workload and stress at these centers.

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Key facts

- Counterfeit medicines are medicines that are deliberately and fraudulently mislabeled with respect to identity and/or source.
- Use of counterfeit medicines can result in treatment failure or even death.
- Public confidence in health-delivery systems may be eroded following use and/or detection of counterfeit medicines.
- Both branded and generic products are subject to counterfeiting.
- All kinds of medicines have been counterfeited, from medicines for the treatment of life-threatening conditions to inexpensive generic versions of painkillers and antihistamines.
- Counterfeit medicines may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient or too much active ingredient, or with fake packaging.

6.0 Our Position

- The autonomous of the Pharmaceutical Regulatory Authority must be based on setting, promoting and then enforcing standards of pharmaceutical practices.
- On that basis, to then address unprofessional practices or unregistered business that result in counterfeit of sub-standards.
- Loop-holes exist in government policy as there have been a number of medical practices that have been provided permits to practice. For example, proliferation of so-called alternative/traditional medical practices without providing additional regulatory tools and capacity to serve these services.
- Government has spent little effort in securing the regulatory bodies' i.e. PRA and the Medical Council of Zambia, resutiing in these loopholes.
- Inability of the regulatory bodies to establish firm policy on setting standards, registration and monitoring of all registered products and licensed practitioners.
- Limited and therefore selective enforcement of regulations due to lack of human, financial, technical and material resources.
- Consequently, the presence on the Zambian market of poor quality or counterfeit has been observed, though the extent is not known.

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- The newly established PRA with the help of WHO,USAID/MSH has taken measures specifically to (a) remove from the all those 'players' not registered under the Pharmaceutical Act(b) to establish the concept of basic testing centers at the selected ports of entry that will be either permanent or mobile (c) to strengthen its operations and resources to enable regular inspections (d) firm pharmacovigilance through out the public and private sector and (e) initiate active post market surveillance activities.
- Political will from government must be there to enforce compliance to the pharmaceutical Act, by also removing political 'interference' in implementation or enforcement of the pharmaceutical Act.

7.0 Recommendations

- The first step is to increase knowledge and understanding in Zambia amongst CSO, policy makers and line ministries and other key role players, as regards to counterfeits and the dangers that surround coming up with anti-counterfeit legislation. However, emphasis should be on strengthening the regulatory implementation, legislative and regulatory infrastructure, enforcement, technology and communication systems in the country
- The Ministry of Health and all stakeholders involved in this issue must ensure that all drugs meet the set established international standards and national standards. Sub-standard medicines do more harm to the people's health and it is unethical to give such medicines to the people.. As we have learnt from the experiences of Uganda and Kenya.
- The Zambian Government should try by all means to establish quality control good laboratories for monitoring of all pharmaceuticals. The locally manufactured and those imported or donated. Mainly, this is to safeguard the lives of people.
- Strengthen drug regulation system of PRA by decentralizing the inspectorate unit-open units through out the country's medicine entry points directly or indirectly through government wings like ZRA and Immigration etc.
- Establish National Drug Quality Control Lab to test all drugs prior to distribution of any drugs and medicines in Zambia.

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- All drugs should be bought only from duly registered Pharmacies (PRA, local Councils and the Police must work towards closing all illegal drug stores in the Country.
- All donations regarding medicines and drugs must be approved by PRA prior to donations and should be drugs duly registered in Zambia and the donations should only be duly registered Health Institutions.
- Sensitive the general public to buy drugs only from duly registered Pharmacies.
- Collaborate with all stakeholders to curb counterfeiting.
- There is need to strengthen the multi-faceted stakeholder approach regarding transparency and accountability in the medicine supply chain.

Conclusion

Developing countries like Zambia should try their best at all costs establish good laboratories for monitoring or checking for quality control for all pharmaceuticals locally manufactured and those imported (entering) or donated to countries to make sure that they meet the set or established international or national standards. Short of that countries will be wasting a lot of money using forex which has been borrowed in a form a loans procuring and distributing to its people sub-standard medications which will do more harm than good to its indigenous people and this is unethical per se to give people drugs not meeting required set international standards.

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