

THREAT POSED BY 2008 ANTI-COUNTERFEIT ACT TO ACCESS OF GENERIC MEDICINES IN KENYA



*Dawa Yangu
Uhai Wangu!
Haki Yangu*

Generic Medicines Are **NOT** "COUNTERFEIT"

Joint statement

Joint statement by MSF, HAI Africa & KELIN on the Kenya Anti-Counterfeit Act 2008 decision

Health activists welcome High Court judgment on anti-counterfeit law

20 April 2012 – After three years of waiting, health activists today welcomed a decision by the High court that the Kenya Anti-Counterfeit Act 2008 was vague and could undermine access to affordable generic medicines. High Court Judge Mumbi Nguni, found that the Act had failed to clearly distinguish between counterfeit and generic medicines.

Justice Mumbi's ruling affirmed a conservatory order issued on April 23, 2010 by Justice Roseline Wendo which stopped the government from implementing the Anti-Counterfeit Act with respect to generic medicines until the case was determined.

"The court has correctly interpreted the Constitution and guaranteed the right to health. This ruling speaks against any ambiguity that serves to undermine access to generic medicines and puts the lives of people before profit", said Patricia Asero, one of the three petitioners.

The High court ruling means that parliament will now have to review the

Act and amend sections that confuse generic medicines with counterfeits and remove ambiguities that may result in arbitrary seizures of generic medicines under the guise of fighting counterfeits. Health activists have vowed to press for those changes to protect access to generic medicines.

"This was a poorly drafted law from the outset that must be urgently reviewed to avoid threatening public health programmes such as the national treatment programme on HIV which is predominantly dependent on access to generic anti-retrovirals", warned Jacinta Nyachae, executive director, AIDS Law Project.

The activists also predict this will set a positive precedent for the entire East Africa region as other countries in this region and the East African Community are considering anti-counterfeiting laws that may threaten generics.

"Kenya is leading the way in protecting access to medicines and public health and we are watching the actions of the East Africa Community member states to see if they follow suit," she added.



Contents

| | |
|---|----|
| Abbreviations | 3 |
| Forward | 4 |
| Executive Summary | 8 |
| | |
| Chapter One: | |
| Threat posed by Anti-Counterfeit Act on Generic Medicines in Kenya | 11 |
| I. “Counterfeiting” Definition Problem | 12 |
| II. Excessive legal responsibility for counterfeiting | 14 |
| III. Power of seizure and storage | 14 |
| IV. Application of the Act to goods in transit | 15 |
| V. Lack of independence of the Board | 15 |
| | |
| Chapter Two: | |
| Access to Medicines as a Component of the Right to Health | 17 |
| | |
| Chapter Three: | |
| Kenya’s Obligations on Anti-Counterfeiting with Regard to the Trips Agreement | 21 |
| | |
| Chapter Four | |
| Summary of Proposals for Amendment | 25 |
| | |
| Conclusion and Call to Action | 37 |



Abbreviations

- TRIPS** Trade-Related Aspects of Intellectual Property Rights
- CSOs** Civil Society Organizations
- PLHIV** Persons Living with HIV
- CIC** Commission on the Implementation of the Constitution
- ALP** Aids Law Project
- NEPHAK** Network of People Living with HIV in Kenya
- IP** Intellectual Property
- INN** International Non-proprietary Name
- WHO** World health Organization



Forward

Many developing countries including Kenya face numerous challenges in the provision of effective health care to its citizens. Millions of people do not have access to even the most basic healthcare services, including safe and effective medicines. This has resulted in a crisis in which diseases such as HIV&AIDS, tuberculosis (TB) and malaria are spreading in countries that have neither the resources nor the facilities to deal with them.

Access to safe and affordable medicines is critical to the enjoyment of the highest attainable standard of health as guaranteed in the Constitution of Kenya 2010. Access to medicines entails having safe medicines; continuously available and affordable at both public and private health facilities including medicine outlets. There are many significant barriers to access to medicines in Kenya; a problem that is deeply-rooted in poverty. One of the factors affecting access to medicines is the high cost of medicines in Kenya. Public interest concerns on the need to address this concern ensured the enactment of provisions in the Industrial Property Act of 2011 that have facilitated increased local production and international supply of generics which

currently constitute about 90% of all medicines in Kenya. The Anti-counterfeit Act enacted in 2008 however contains key provisions that threaten this access to the more affordable generic medicines in Kenya and the region.

The fears of many Kenyans on the quality and effectiveness of medicines is being continuously exploited to justify stronger IP enforcement. Claims that IP enforcement will address the existing problem of substandard and fake medicines are misleading. This confusion is being experienced even by the WHO. There is need for community voices in the debate around IP and access to medicines particularly in Kenya where key sections of the Anti-Counterfeit Act must be clarified or amended if Kenyan patients are to continue accessing quality medicines at affordable prices.

On behalf of NEPHAK, ALP and KELIN; all being Civil Society Organizations working to advance HIV related human rights; we applaud the decision of Kenya's High Court which ruled that the Anti-counterfeit Act violates the right to life, human dignity, and health, as outlined in the Constitution of Kenya. This judgment is not just important for people living with

HIV, but to all Kenyans who depend on generics to treat all kinds of illnesses. We urge the relevant policy makers to amend the provisions of the Anti-Counterfeit ACT and take all necessary measures to ensure access to affordable and essential medicines including generic medicines. We are calling on the government to fully utilize the flexibilities contained in the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) in order to ensure long term availability, accessibility and affordability of quality medicines in Kenya for the full enjoyment of the highest attainable standard of health guaranteed in Article 43(1)a of the Constitution of Kenya, 2010.

This booklet has been developed with the broad objective of enhancing the understanding of civil society, in order to influence and inform public debate. We are confident that this will boost advocacy initiatives for the amendment of the contentious provisions that threaten access to generic medicines in Kenya.

This booklet has been written with great care and concern to meet the requirements for easily understandable

public information with regard to the “generics are not counterfeit campaign” that seeks to advocate to the amendment of the provisions of the Act that pose a threat on access to medicines. A great task of this nature cannot be completed without the constant support of many people and I take this opportunity to thank all of them sincerely.

Allan Maleche
Executive Director
KELIN



Kenya's Obligations on Anti-Counterfeiting with regard to the TRIPS Agreement



Kenya enacted a law that purported to address drug counterfeiting, but in fact dramatically expanded IP enforcement. Such laws are dangerous to countries like Kenya which rely heavily on generic medicines.

The definition of counterfeiting under the Anti-counterfeit Act is needlessly broad and goes beyond the obligations under the Trade Related Aspects of Intellectual Property Rights (TRIPs) agreement, signed under the auspices of the World Trade Organization (WTO) member states which include Kenya.

Noteworthy, during the Doha Declaration on TRIPS and public health, members of

the (WTO) agreed that countries could invoke the flexibilities contained in the TRIPS Agreement to facilitate access to life-saving medications for their people. Unfortunately, the victory at Doha continues to be undermined by laws and policies that allow adoption of a TRIPS-plus intellectual property regime. This is the situation as seen through the Patricia Asero case which raises the question of states' duties to protect and promote the rights to health and life of its people in as far as access to affordable medicines is concern.

As CSO's working to advance health rights, we call upon the government to review, reform or repeal as needed the problematic sections in the Anti-Counterfeit Act as well as other related laws that could hamper access to more affordable generic medicine. Failure or reluctance of the government to invoke the flexibilities contained in the TRIPS Agreement to facilitate access to generic medicines for its citizens would amount to a violation of the obligation to safeguard the rights to health and life as guaranteed under the Constitution and International instruments.

Jacinta Nyachae
Executive Director
Aids Law

Access to medicines as a component of the right to health.



The Kenya Constitution 2010 came with an expanded Chapter on Bill of Rights, including the right to the highest attainable standard of health (Article 43). For people living with HIV and those affected by TB and AIDS, this is a huge milestone. Legislations and policies that promote the ambiguity in definitions of ‘generics’ versus ‘counterfeits’ as witnessed in the Kenyan Anti counterfeit Act threaten the access to essential medicines for many people in the country who depend on them. This is particularly true for Kenya where about 80 percent of the essential medicines in the country are not branded medicines. People living with HIV, those affected by TB and Malaria are recipients of WHO-prequalified medicines for treatment and for improved quality of life. All stakeholders in health sector need to ensure that access to treatment is not interfered with as this directly impacts of the health of the Kenyans protected by the provisions in the constitution.

Nelson Otwoma
Executive Director
NEPHAK




Executive Summary

Access to affordable medicines in the public health sector in Kenya and other developing countries plays a critical role in treating and managing HIV, tuberculosis and malaria among other diseases. Generic drugs play an important role in the delivery of healthcare services in Kenya because of their affordability and availability. It is estimated that 90% of all medicines in Kenya are generic and according to the Anti-Counterfeit Act (the ACT) such treatments must be banned.

The ACT, enacted in 2008 amidst strong opposition from health Civil Society Organizations (CSOs) and People Living with HIV (PLHIV) in Kenya, poses a severe threat on access to generic pharmaceuticals in Kenya and the region. Some specific reasons why the ACT presents a threat on access to generic medicines in Kenya can be summarized as:

- The broad definition of counterfeits under the ACT can be used to restrict manufacture, sale and distribution of generic drugs in Kenya.
- The ACT criminalizes manufacturing, production and packaging of similar products which will affect the availability of generic drugs in Kenya.
- The ACT gives inspectors appointed by the ACA Board excessive powers to detain suspected counterfeit products which could include generics drugs; yet they are not qualified to determine the quality of drugs.
- The ACT does not specify the duration within which detained goods are held. This could result in the expiry of drugs that have been detained or result in unnecessary delay and potential interruption in treatment.
- The ACT empowers the government of Kenya to detain goods being transported to other countries through Kenya. This further threatens access to medicines region which would extend all the above threats to the region.



The Constitution of Kenya 2010 guarantees the right to the highest attainable standard of health which encompasses access to medicines. The High Court, in the case of *Patricia Asero Ochieng and 2 others vs. Attorney General and Another (Petition No. 409 of 2009 in the High Court of Kenya)*, ruled that Sections 2, 32 and 34 of the Anti-Counterfeit Act, threatened to violate the right to health guaranteed under Art. 43(1)a of the Constitution. It was further held that the definition of “counterfeit” in the ACT is likely to be read as including generic medication and was therefore likely to adversely affect their manufacture, sale, and distribution.

The court therefore ordered the state to reconsider the provisions of Section 2 of the ACT alongside its Constitutional

obligations and make appropriate amendments to ensure that the rights of those dependent on generic medicines are not put in jeopardy.

Civil Society actors including communities of are calling upon the relevant policy makers to amend the provisions of the Anti-Counterfeit Act and take all necessary measures to ensure access to affordable and essential medicines including generic medicines in compliance with the judgment of the High Court of Kenya.

Chapter 1



Threat posed by Anti-Counterfeit Act on Generic Medicines in Kenya

The Kenyan parliament enacted the Anti-Counterfeit ACT No. 13 of 2008, hereinafter referred to as the ACT, in order to ban trade in counterfeit goods.

A counterfeit can generally be described as an imitation of a genuine product; which is often more valuable, with the intent to deceive or defraud.

For example, in Kenya many people prefer to buy CD/DVD copies from street vendors that are readily available at substantively lower prices than the original ones sold by the authorized distributors. Such production and marketing, which is done without the consent of the rightful owner, is considered illegal and punishable under the ACT. In most cases, counterfeit products have a reputation for being lower quality and sometimes they do not work at all. They are intended to deceive a consumer who may be unable to access or afford the legitimate item.

Intellectual Property Rights (IPRs) are the legally recognized exclusive rights to creations of the mind. Under intellectual property law, owners are granted certain exclusive rights to a variety of intangible assets, such as musical, literary, and artistic works; discoveries

and inventions; and words, phrases, symbols, and designs. Common types of intellectual property rights include copyright, trademarks, patents, industrial design rights, trade dress, and in some jurisdictions trade secrets. These rights are protected by TRIPS, of World Trade Organization (WTO). They were adopted in Kenya through the Industrial Property Act of 2011, and are generally limited to a period of time. Once the rights are expired others are able to benefit from them.

In relation to pharmaceutical products, when a new drug is developed the creator of such drug has the right to produce and sell the drug, this right is legally protected. This exclusive right given to the creator is referred to as a patent and is protected for a number of years. When the period of protection for a branded medicine expires it is a common practice in relation to public health to make available medicines which are similar versions of the drug. These similar medicines are known as generic medicines and are clinically intended to be interchangeable with the branded medicines as they produce the same effect. Generic medicines must meet the strict medical standards for quality and must also work the same way the brand-name



Threat posed by Anti-Counterfeit Act on Generic Medicines in Kenya

product does. The generic version contains exactly the same active or key ingredients. It may only vary in appearance, flavor, or some of the inactive ingredients. Generic medicines are genuine products that can be produced legally.

Since generic drug makers do not develop a drug from scratch or conduct clinical trials already performed by the brand manufacturer, the costs to bring the drug to market are less; therefore, generic drugs are usually less expensive than brand-name drugs. As a result of the availability of generic medicines in Kenya from 2001, the prices of HIV, TB and Malaria treatment has been reduced by approximately 80% and as a consequence significantly more people now have access to life saving treatments. For example When Kenya enacted the Intellectual Property ACT in May 2002 allowing for the importation of products that have been “legitimately” put on the market, the price of the first-line ARV drug regimen dropped from US\$825 to US\$300 per patient per year.

The Anti-counterfeit Act enacted into law in 2008 solicited strong opposition from health civil society organizations (CSOs) and PLHIVs in Kenya who were mainly concerned that the ACT as

enacted threatened access to generic pharmaceuticals in Kenya and the region. Some of the major issues with the ACT that pose a risk on the continued access to generic medicines in Kenya are as follows:

I. “Counterfeiting” Definition Problem

As mentioned earlier, generic medicines are similar to the branded medicines and are clinically intended to be interchangeable with the branded medicines as they produce the same effect.

The use of the terms “identical or substantially similar” and “colorable imitation” in the definition of counterfeiting is problematic in the case of medicines, as generics are intentionally identical in composition and, for clinical reasons, often also in appearance. The term “confusingly similar” is also problematic for medicines, as often the branding is derived from the International Nonproprietary Name (INN).

The INN is a unique name that is used to identify pharmaceutical substances or active ingredients. This INN name is publicly used and cannot be claimed by an individual. E.g. The

Threat posed by Anti-Counterfeit Act on Generic Medicines in Kenya

INN Lopinavir/r, for example, is a fixed dose combination drug which is widely used in Kenya for HIV treatment, is produced by several manufacturers in different countries. It is marketed as Kelatra and Aluvia. Under the ACT, registration by one of these manufacturers would limit the sale of the same drug by another manufacturer. Given that the vast majority of drug patents are not registered in developing countries like Kenya, the enforcement of the ACT could reduce the range of generic medicines available to doctors and their patients.

As per definition in the ACT “goods that are identical or substantially similar” are counterfeits. Therefore this broad definition of counterfeits under the ACT can be used to restrict manufacture, sale and distribution of generic drugs in Kenya where a branded medicine may be registered for use in the market. The High Court Judge Mumbi Ngugi in her ruling observed that “the ACT is vague and could undermine access to affordable generic medicines since it failed to clearly distinguish between counterfeit and generic medicines.”

Counterfeiting, according to the Act, means taking the following actions without the authority of the owner of intellectual property right subsisting in Kenya in respect of protected goods-

- (a) the manufacture, production, packaging, re-packaging, labelling or making, whether in Kenya, of any goods whereby those protected goods are imitated in such manner and to such a degree that those other goods are identical or substantially similar copies of the protected goods;*
- (b) the manufacture, production or making, whether in Kenya, the subject matter of that intellectual property, or a colourable 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 license;*
- (c) the manufacturing, producing or making of copies, in Kenya, in violation of an author's rights or related rights;*



Threat posed by Anti-Counterfeit Act on Generic Medicines in Kenya

II. Excessive legal responsibility for counterfeiting

Trade-related disputes such as those relating to counterfeiting are generally civil in nature, as opposed to criminal. Cases of a civil nature generally arise from a dispute between two or more individuals, businesses, etc. which result in payment of money by one party to another for the harm that has been caused by the other. Hence this means where someone has an issue with another person copying their product he can file a case for compensation for losses incurred as a result of such action and prove this allegations before the court.

The penalties provided for offences under the ACT are overly punitive as they impose criminal sanctions on civil private rights that should be rightfully enforced individually using civil procedures. Fear of having a criminal claim brought under the ACT is likely to discourage local Research and Development (R&D), the production, importation and exportation legitimate generics.

Kenya has the fourth highest burden of the AIDS epidemic globally, but remains hugely dependent on imported pharmaceutical and medical products. UNAIDS Executive Director, Michel Sidibé, has called for broader support for the local production of antiretroviral (ARVs) which is vital to secure the continued access to life-saving treatment for people already accessing ARVs, and the many more who still need access to treatment.

III. Power of seizure and storage

The ACT gives broad powers to the authorities to detain any goods suspected of being counterfeit and goes beyond the provisions outlined in the Constitution. Further, the ACT does not provide specific timeframes within which the detained goods should be released even after the dispute is resolved. These broad powers given can be abused and may result in unwarranted delays and the deterioration of products especially public health sensitive provisions such as medicines or test kits which should not to be held for more than 10 days.

Threat posed by Anti-Counterfeit Act on Generic Medicines in Kenya

IV. Application of the ACT to goods in transit

Legally, goods cannot be detained in transit on the grounds of IP infringement — trademarks and patents are specific to a particular territory. The ACT contains provisions with such a broad scope that it includes an offence relating to goods on transit. Goods in transit being imported to other countries especially within the East African region through Kenya could be detained.

By enforcing this, authorities in Kenya will not only be extending their powers on issues of other countries but will be utilizing public resources to enforce private rights of individuals based in other countries whereas these resources can be put to better use locally. This, therefore, extends all the above mentioned threats to the wider region, thus further threatening access to generic medicines beyond the Kenyan boundaries where such products may not be considered counterfeit.

V. Lack of independence of the Board

The provisions of the ACT allow private sector actors to be part of the Board. This raises serious concerns about conflicts of interest as they are likely to have strong commercial interests they wish to protect, and their involvement could conflict with the objectivity and independence of the Board. The provisions of this ACT also allow the Board and the Anti-Counterfeit Agency to receive gifts, grants and donations from agencies other than the government which makes them susceptible/vulnerable to allegations of corruption.

The Industrial Property Act, 2001 whilst protecting creators/producers rights also including provisions to ensure access to medicines. This Act facilitated increased local production and international supply of generics which constitute about 90% of all medicines in Kenya. As discussed above, the Anti-Counterfeit Act contains provisions that pose a risk to this continued access for generic drugs.

Chapter 2

MEDICINE

AL
LTD.

u, Kenya

Each caplet contains
Sulphamethoxazole B.P. 800mg
Trimethoprim B.P. 160mg

Sulfran-DS
CAPLETS

Store under normal room temperature (15 - 30°C) in a dry place. Protect from direct sunlight. Keep all medicines out of reach of children.

Dosage
As directed by the physician

500 Caplets
Manufactured by
LINIV RSAL

Batch No: **120780**
Mfg Date: **04/2011**
Exp Date: **03/2014**



CONSIGNEE : PHILLIPS HEALTHCARE SE
(MOMBASA ROAD, WAREHOUSE)

ITEM :
B/No : 120780
MFG DATE : 04/2011
EXP DATE : 03/2014
QUANTITY : JARS X 500'S
WEIGHT : KG
CARTON No. : 17

Access to Medicines as a Component of the Right to Health

Access to medicines as part of the right to the highest attainable standard of health is wellfounded in international, regional and domestic law.

In Kenya the right to health is entrenched and provided for in the Constitution of Kenya 2010. Article 43(1)a states that “Every person has the right to the highest attainable standard of health, which

includes the right to health care services, including reproductive health care.

It is important to note that in framing the right to health, the Kenyan Constitution adopted the right to the highest attainable standard of health recognized in regional and international human rights instruments. Additionally Article 2(6) provides that any treaty or convention ratified by Kenya shall form part of the laws of Kenya.

| Instrument | Provisions |
|---|--|
| World Health Organization (WHO) Constitution | “The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being.” It further provides that “Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.” |
| Article 25 (1) Universal Declaration of Human Rights (UDHR) | States that “Everyone has the right to a standard of living adequate for the health of himself and of his family, including food, clothing, housing and medical care and necessary social services” |
| Article 12 (1) of the International Covenant on Economic, Social and Cultural Rights (ICESCR) | Provides for “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health”. The steps to be taken by states to achieve the full realization of this right are provided and include the right to prevention, treatment and of disease, and the right to health facilities, goods and services. Provision of essential drugs has been identified by the Committee of ICESCRs as one of the minimum core obligations of governments. |
| Article 16 of the African Charter on Human and People’s Rights (ACHPR) | Provides that ‘Every individual shall have the right to enjoy the best attainable state of physical and mental health’ |



Access to Medicines as a Component of the Right to Health

In 2008 immediately after the enactment of the Anti-Counterfeit Act in Kenya, the case of Patricia Asero Ochieng and 2 Others v. the Attorney General & Another (Petition No. 409 of 2009 in the High Court of Kenya), was filed to challenge the constitutionality of certain provisions of the ACT. The Petitioners were three persons living with HIV and relying on generic ARVs provided under government's programmes. The petitioners argued that Section 2 of the ACT confused generic drugs with counterfeit medicine and, if implemented, the ACT would inflict civil and criminal penalties on generic medicine manufacturers and severely restrict access to affordable medicine in Kenya. Such restrictions would violate the petitioners' right to life, health and human dignity under the Articles 26(1), 28 and 43(1) a of the Constitution.

In framing the right to health, the Kenyan Constitution adopted the right to the highest attainable standard of health recognized in regional and international human rights instruments which has provided under

Article 2 (6) that any treaty or convention ratified by Kenya shall forms part of the laws of Kenya. The WHO Constitution and Preamble state that; "The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being." It further provides that "Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity." Article 12 of the International Covenant on Economic Social and Cultural Rights equally provides for the right to "highest attainable standard of physical and mental health". Similarly Article 16 of the African Charter on Human and People's Rights provides that 'Every individual shall have the right to enjoy the best attainable state of physical and mental health'.

Access to medicines is a fundamental element of the rights to health. This is the position of the UN special rapporteur on health, who was enjoined in this case as amicus curiae (a friend of the court) in fulfillment of his mandate in the Human Rights council. In his submissions Mr. Anand Grover submitted that "while the



Access to Medicines as a Component of the Right to Health

objective of the ACT is to prohibit trade in counterfeit goods, it is likely, as currently written, to endanger the Constitutional right to health.”

The High Court agreed with the above submissions and ruled in favor of the petitioners and declared Sections 2, 32 and 34 of the ACT unconstitutional. It also held that the definition of “counterfeit” in the ACT conflated generics with counterfeits and was therefore likely to adversely affect the manufacture, sale, and distribution of life saving generic drugs. This in turn would hamper the availability of the

generic drugs and pose a threat to the petitioners’ right to life, dignity and health under the Constitution.

The High Court ordered the state to reconsider the provisions of the ACT alongside its Constitutional obligations and make appropriate amendments to ensure that the rights of those dependent on generic medicines are not put in jeopardy.

Chapter 3



Kenya's Obligations on Anti-Counterfeiting with Regard to the TRIPS Agreement

The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) sets out the minimum standards of protection in relation to IPRs to be provided by World Trade Organization (WTO) member states, which includes Kenya. It describes the subject matter to be protected, the rights to be conferred including permissible exceptions to those rights and the minimum duration of protection. In the TRIPS Agreement, there are different categories of IPRs and the agreement provides distinct rights, obligations, exceptions and limitations for each of these categories as each category protects different subject matter and has different effects.

Coca-Cola *Coca Cola*

When you look at these two trademarks you can easily identify which is the genuine one and which is the fake one.




Similarly, though a bit more difficult, you may also be able to identify the fake phone and the real one in this image. With medicines, this is even more difficult as illustrated here



The provisions of the TRIPS Agreement in relation to counterfeiting are only limited to "counterfeit trademark goods" and "pirated copyright goods" and NOT in respect of other types of infringement concerning trademarks (e.g. passing off, "confusingly similar trademarks", improper use of trademark) or copyright (e.g. substantial similarity, adaptation without the author's permission). These are civil disputes and there is no obligation under TRIPS to subject such disputes to border measures or to criminal procedures and penalties.

More importantly, the provisions do not apply to other intellectual property rights (e.g. patent and plant variety protection infringements). One reason for this



differentiation is that infringement in the case of trademark counterfeiting and copyright piracy may be determined with ease on the basis of visual inspection of imported goods since the infringement will be apparent “on its face”. The term can therefore only be used in relation to the name of a medicine or the shape or colour of that medicine. In this way legitimately registered generic medicines could be assumed as counterfeit solely because has a similar look or name to another pill.

As explained above, infringements of trademarks and copyrights are easily identifiable as opposed to the other IP infringement where more expertise and investigation is necessary to determine whether infringement has taken place. Such technical expertise is required in relation to medicines and drug regulatory authorities are mandated with that task.

The TRIPS Agreement additionally recognizes that “intellectual property rights are private rights” and thus the responsibility for enforcement lies with the right holder.

Kenya has enacted the Industrial Property Act, The Copyright Act, The Seed and Plant Varieties (Plant Breeders Rights) Regulations, The Seeds and Plant Varieties Act, The Trade Marks Act and The Competition Act, which sufficiently address infringements of intellectual property with expert regulatory authorities established to determine such matters. Therefore, counterfeiting provisions in the ACT should only be limited to “counterfeit trademark goods” and “pirated copyright goods” and NOT in respect of other types of infringement addressed in other legislations.

Adopting TRIPS-plus measures (provisions that are tougher or more restrictive than those required by the TRIPS Agreement) in the guise of addressing counterfeiting; as contained in the provisions of the Kenya Anti-counterfeit ACT, is likely to result in barriers to legitimate trade and restrict local industrial development.

MINISTRY OF MEDICAL SERVICES HOMA BAY DISTRICT CITIZENS HEALTHCARE SERVICE

SERVICES HOSPITAL DELIVERY CHARTER

HOA BAY DISTRICT HOSPITAL IS COMMITTED TO OFFERING HIGH QUALITY INTEGRATED MEDICAL CARE SERVICES & TRAINING OF COMPETENT HEALTH CARE WORKERS
 HOMA BAY DISTRICT HOSPITAL OFFERS HIGH QUALITY CLIENT FRIENDLY INTEGRATED MEDICAL CARE SERVICES & TRAINING OF HIGH QUALITY MEDICAL SERVICES
 PERSONNEL TO PROVIDE CONCEPT ENVIRONMENT THAT GUARANTEES ACTIVE PARTICIPATION IN THE PROVISION OF HIGH QUALITY MEDICAL SERVICES
 CLIENTS TO PROTECT PROFESSIONALISM, ETHICS, EXCELLENCE, TRANSPARENCY, ACCOUNTABILITY, INTEGRITY/HONESTY, PARTNERSHIP/TEAMWORK.

| SERVICES | PATIENT/CLIENT EQUIPMENT | USER CHARGES | TIME | SERVICES | PATIENT/CLIENT EQUIPMENT | USER CHARGES | TIME |
|---|---|---|---------------------|---|--|---------------------------------|--|
| CONSULTATION WITH THE CUSTOMER CARE OFFICER | CONSCRIPTION FORMS THE CLIENT | FREE | UP TO 5 MINUTES | CONSULTATION (NIGHT-SERVICES) | * PASS BOOK * REFERRAL NOTE * PAYMENT RECEIPT | 50/- 100-300/- 300-2000/- | UP TO 30 MINUTES |
| PROVISION OF HOSPITAL CHARGES | CONSCRIPTION INSCRIPTION FORM | FREE | UP TO 20 MINUTES | MAJOR PROCEDURES | * COOPERATION FROM PATIENT/RELATIVES * PAYMENT RECEIPT * REFERRAL NOTE/INIP CARD * PATIENT FILE * CONSENT * PAYMENT RECEIPT | 450-1000/- 50-200/- | 30-60 HOURS UP TO 24 HOURS UP TO 30 MINUTES |
| PHARMACY SERVICES | PHARMACY CHARGE SHEET SUP CARD | 15/- | UP TO 10-20 MINUTES | * ACCOMMODATION | 1500-15000/- | | |
| DIAGNOSTIC SERVICES | PHARMACY CHARGE SHEET SUP CARD | 70/- | UP TO 20 MINUTES | * PROCEDURE | | | |
| LABORATORY SERVICES | PHARMACY CHARGE SHEET SUP CARD | 70/- | UP TO 20 MINUTES | | | | |
| WOUND HEALING SERVICES | * PASS BOOK * REFERRAL LETTER * PAYMENT RECEIPT | 20-500/- | UP TO 20 MINUTES | OBSTETRIC SERVICES | * EMERGENCY * NON-EMERGENCY SERVICES * ADMISSION & ASSESSMENT * PROCEDURE | FREE 50-2000/- | UP TO 24 HOURS UP TO 30 MINUTES |
| ART PROGRAM | * PRESCRIPTION * PAYMENT RECEIPT | FREE | UP TO 30 MINUTES | WARRANTY SERVICES | * NORMAL DELIVERY * MAJOR SURGERY/EPIDEMIOL * MAJOR SURGERY (C/S) | 500/- 50/- 2500/- | UP TO 1 MIN-10-15 MIN |
| WOUND HEALING SERVICES | * MATERNAL CHILD HEALTH CARD * PAYMENT RECEIPT | FREE | UP TO 30 MINUTES | * CHILDREN 5 YEARS | * COOPERATION FROM PATIENT/RELATIVES * FILE * CONSENT * COOPERATION FROM PATIENT/RELATIVES * FILE * PAYMENT RECEIPT/INIP CARD * COOPERATION FROM RELATIVES * FRESH BODY/PARTICULARS | FREE 20-500/- | UP TO 30 MINUTES |
| WOUND HEALING SERVICES | * INVESTIGATION REQUEST FORM * PAYMENT RECEIPT | 20 100-300/- 500-1000/- | UP TO 30 MINUTES | * ADULT & CHILDREN 5 YEARS | * FREE 200/- PER DAY | | UP TO 1 HOUR |
| WOUND HEALING SERVICES | * REQUEST FORM * PAYMENT RECEIPT | FREE 50-600/- 500-300/- 350-1000/- | UP TO 20 MINUTES | * INFANT SERVICES | | | |
| WOUND HEALING SERVICES | * PASS BOOK * REFERRAL LETTER * PAYMENT RECEIPT | 250-1000/- 1500-7500/- | UP TO 10 MINUTES | * HERBALING * BODY STORAGE * DENTONALOGIC SERVICES * PLAGSTER APPLICATION * ACUTHEMS * SPECIAL CLINIC * INOPIC, SOIC, POPC, DIAGNOSTIC CLINIC, PSYCHIATRY CLINIC * DENT SERVICES * CONSULTATION * PROCEDURES | 150/- 1000/- | | UP TO 15 MINUTES UP TO 30 MINUTES UP TO 30 MINUTES |

ALL HEALTH SERVICES TO UNDER 5 YEARS TREATMENT FOR MALARIA, TB, HIV/AIDS AND EPIDEMICS ARE FREE
 ANY SERVICE THAT DOES NOT CONFORM TO THE ABOVE STANDARD OR AN OFFICER WHO DOES NOT LEAVE UP TO THE COMMITMENT
 STATED ABOVE SHOULD BE REPORTED TO THE FACILITY ADMINISTRATOR / MEDICAL SUPERINTENDENT
 TEL: 0723 488568 / 0727952276 / 0726000350 / 07222 4480718
 P.O. BOX 52-40300, HOMA BAY KENYA.
HUDUMA BORA NI HAKI YAKO !!

Chapter 4



Summary of Proposals for Amendment

| CURRENT WORDING OF SECTION | PROPOSED AMENDMENTS | REMARKS/JUSTIFICATIONS |
|--|--|---|
| PART ONE-PRELIMINARY | | |
| <p>“Counterfeiting” means taking the following actions without the authority of the owner of intellectual property right subsisting in Kenya in respect of protected goods-</p> <p>(a) the manufacture, production, packaging, re-packaging, labeling or making, whether in Kenya, of any goods whereby those protected goods are imitated in such manner and to such a degree that those other goods are identical or substantially similar copies of the protected goods;</p> <p>(b) the manufacture, production or making, whether in Kenya, 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 license;</p> | <p>Counterfeiting means acts done willfully and on a commercial scale in relation to counterfeit trademark goods and pirated copyright goods.</p> <p>Counterfeit trademark goods refer to goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered [in Kenya] 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 Kenya;</p> <p>Pirated copyright goods refer to goods which are copies made without the consent of the right holder or persons duly authorized by the right holder in Kenya and which are made directly or indirectly from an article where the making of that copy would have constituted an infringement of a copyright or a related right in Kenya.</p> | <p>The proposed amendment is in line with Article 51 and Article 61 of the TRIPs Agreement.</p> <p>The proposed definition of Counterfeit trademark goods and Pirated copyright goods is drawn from footnote 14 of Article 51 of the TRIPs Agreement.</p> |

Summary of Proposals for Amendment

| CURRENT WORDING OF SECTION | PROPOSED AMENDMENTS | REMARKS/JUSTIFICATIONS |
|---|--|---|
| <p>(c) the manufacturing, producing or making of copies, in Kenya, in violation of an author's rights or related rights;</p> <p>(d) in relation to medicine, the deliberate and fraudulent mislabeling of medicine with respect to identity or source, whether or not such products have correct ingredients, wrong ingredients, have sufficient active ingredients or have fake packaging;</p> <p>Provided that nothing in this paragraph shall derogate from the existing provisions under the Industrial Property Act.</p> | <p>Counterfeiting and Counterfeiting goods provisions under this Act shall not apply to goods in transit or being exported from Kenya.</p> <p>No other form of intellectual property protection is covered under this Act. This Act does not apply to civil trademark infringement matters such as confusingly similar goods, in particular confusing similar trade names derived from international non-proprietary names for medicines or confusingly similar trade dress or appearance (size, shape, and color) of medicines that are therapeutically equivalent.</p> | |
| <p>"counterfeit goods" means goods that are the result of counterfeiting, and includes any means used for purposes of counterfeiting;</p> | <p>Delete the whole section</p> | <p>With the above amendment of "counterfeiting", there is no need for a definition of counterfeit goods", "intellectual property" or "protected goods" because the scope of this Act becomes clear. This will exclude the rights protected under the Industrial Property Act and the Seeds and Plant Varieties Act, which are currently included.</p> |

Summary of Proposals for Amendment

| CURRENT WORDING OF SECTION | PROPOSED AMENDMENTS | REMARKS/JUSTIFICATIONS |
|---|--------------------------|------------------------|
| <p>“intellectual property right” includes–</p> <ul style="list-style-type: none"> (a) any right protected under the Copyright Act; (b) any plant breeders’ right granted under the Seeds and Plant Varieties Act; (c) any right protected under the Trade Marks Act; and (d) any right protected under the Industrial Property Act; | | |
| <p>“protected goods” means–</p> <ul style="list-style-type: none"> (a) goods featuring, bearing, embodying or incorporating the subject matter of an intellectual property right with the authority of the owner of that intellectual property right, or goods to which that subject matter has been applied by that owner or with his authority; (b) any particular class or kind of goods which, in law, may feature, bear, embody or incorporate the subject matter of an intellectual property right only with the authority of the owner of that intellectual property right, or to which that subject matter may in law be applied, only by that owner or with his authority, but which has not yet been manufactured, produced or made, or to which that subject matter has not yet been applied, with the authority of or by that owner, whichever is applicable; | Delete the whole section | |

Summary of Proposals for Amendment

| CURRENT WORDING OF SECTION | PROPOSED AMENDMENTS | REMARKS/JUSTIFICATIONS |
|---|--------------------------|------------------------|
| <p>“intellectual property right” includes–</p> <ul style="list-style-type: none"> (a) Any right protected under the Copyright Act; (b) Any plant breeders’ right granted under the Seeds and Plant Varieties Act; (c) Any right protected under the Trade Marks Act; and (d) Any right protected under the Industrial Property Act; | | |
| <p>“protected goods” means–</p> <ul style="list-style-type: none"> (a) goods featuring, bearing, embodying or incorporating the subject matter of an intellectual property right with the authority of the owner of that intellectual property right, or goods to which that subject matter has been applied by that owner or with his authority; (b) any particular class or kind of goods which, in law, may feature, bear, embody or incorporate the subject matter of an intellectual property right only with the authority of the owner of that intellectual property right, or to which that subject matter may in law be applied, only by that owner or with his authority, but which has not yet been manufactured, produced or made, or to which that subject matter has not yet been applied, with the authority of or by that owner, whichever is applicable; | Delete the whole section | |

Summary of Proposals for Amendment

| CURRENT WORDING OF SECTION | PROPOSED AMENDMENTS | REMARKS/JUSTIFICATIONS |
|---|-----------------------------|--|
| PART TWO – ESTABLISHMENT POWERS AND FUNCTIONS OF THE AGENCY | | |
| <p>Section 6 Board of the Agency (1) The management of the Agency shall vest in a board which shall consist of –</p> <p>(k) The chief executive of the Kenya Association of Manufacturers or his representative</p> | Delete the whole section | The inclusion of the private sector actors raises serious concerns about conflict of interest as they have strong commercial interests which they wish to protect and their involvement could conflict with the objectivity and independence of the board |
| <p>Section 7 Powers of the Board</p> <p>The Board shall have all powers necessary for the proposer performance of its functions under this Act and in particular, but without prejudice to the generality of the foregoing, the board shall have power to –</p> <p>(d) receive any grants, gifts, donations or endowments on behalf of the agency and make legitimate disbursements therefrom</p> | Delete Section sub-para (d) | The agency should only be funded by the government and should not be allowed to receive any other contributions or gifts especially from private sector actors. This will eliminate vulnerability or susceptibility of corruption allegations and promote objectivity. |

Summary of Proposals for Amendment

| CURRENT WORDING OF SECTION | PROPOSED AMENDMENTS | REMARKS/JUSTIFICATIONS |
|---|---|--|
| PART FOUR – INSPECTION | | |
| Section 23 Powers of Inspectors | Inspectors should only be allowed to exercise powers under Section 23 upon a court issuing a warrant | This Section is unconstitutional. Section 40(2) of the Kenya Constitution states: (2) Parliament shall not enact a law that permits the State or any person— (a) to arbitrarily deprive a person of property of any description or of any interest in, or right over, any property of any description; |
| Section 25 (3) and (4) Duty of inspector upon seizure of goods | A reasonable time-frame should be allocated within which the Court should make a determination. | It is only fair that there is a time frame within which the Court should make a determination. Without a time frame court proceedings could continue indefinitely. In determining the time frame it should also be considered that the goods may be perishable. |
| Section 26 (5) Where the subsistence of intellectual property right in respect of suspected counterfeit goods or the title or interest in intellectual property right is in issue, the complainant shall be presumed to be the owner of the copyright of | Where the existence of an intellectual property right in respect of suspected counterfeit trademark goods or pirated copyright goods or the title or interest in intellectual property is in issue, the complainant shall be required to prove ownership or entitlement in accordance | It should be the task of the complainant to prove that the complainant owns the intellectual property rights he/she seeks to protect, since it is the complainant that is asserting the right. If one claims that a right has been violated, they must first prove entitlement of that right. |

Summary of Proposals for Amendment

| CURRENT WORDING OF SECTION | PROPOSED AMENDMENTS | REMARKS/JUSTIFICATIONS |
|---|---|--|
| <p>related right or, as the case may be, the exclusive licensee of any such right, until the contrary is proved</p> | <p>with the relevant provisions of any intellectual property legislation for the time being in force</p> | |
| <p>PART FIVE – COUNTERFEIT GOODS</p> | | |
| <p>Section 32</p> | <p>It shall be an offence for any person to willfully and on a commercial scale: manufacture, produce or make any counterfeit trademark good or pirated copyright goods; sell, hire out, barter or exchange, or offer or expose for sale, any counterfeit trademark good or pirated copyright goods; expose or exhibit any counterfeit trademark good or pirated copyright goods; distribute any counterfeit trademark good or pirated copyright goods; Import any counterfeit trademark good or pirated copyright goods.</p> <p>Section 32 should also make provision for de minimis imports (minor/insignificant quantities) as allowed by Article 60 of the TRIPS Agreement. Article 60 of the TRIPS Agreement states:</p> | <p>The current Section 32 is TRIPS plus. It will implicate those that unknowingly deal with counterfeit goods. Further the prohibition extends to goods in transit/transshipped and those exports from Kenya. Such a provision has extensive implications for Kenya as it will have to spend significant resources in dealing with counterfeit goods that are not intended for use in Kenya. This means Kenya will be utilizing its resources to extend its jurisdiction by applying its law to goods destined for other countries; whether or not they have similar IP protection. With these types of provisions, other countries, especially the least developed countries in the region, may refuse to use Kenya as a transit port, which may entail significant trade losses for Kenya.</p> |

Summary of Proposals for Amendment

| CURRENT WORDING OF SECTION | PROPOSED AMENDMENTS | REMARKS/JUSTIFICATIONS |
|--|---|--|
| | <p>"Members may exclude from the application of the above provisions small quantities of goods of a non-commercial nature contained in travellers' personal luggage or sent in small consignments."</p> | <p>Section 32 should only apply in cases where an act is done willfully or on a commercial scale and should NOT extend to goods in transit/transhipped and exports from Kenya.</p> |
| <p>Section 34 Powers of the Commissioner</p> | <p>Rights of the defendant (to whom the detained goods belong) should be spelt out clearly.</p> | <p>It is unclear what happens to the goods that are detained under Section 34. In particular the rights of the defendant (to whom the detained goods belong) with regard to the time frame within which the court must make a determination that the goods are counterfeit and if they are not counterfeit then the goods should be released.</p> <p>In this regard, due note should be taken of Article 55 of the TRIPS Agreement which states the following: Duration of suspension:</p> |

Summary of Proposals for Amendment

| CURRENT WORDING OF SECTION | PROPOSED AMENDMENTS | REMARKS/JUSTIFICATIONS |
|----------------------------|---------------------|---|
| | | <p>"If, within a period not exceeding 10 working days after the applicant has been served notice of the suspension, the customs authorities have not been informed that proceedings leading to a decision on the merits of the case have been initiated by a party other than the defendant, or that the duly empowered authority has taken provisional measures prolonging the suspension of the release of the goods, the goods shall be released, provided that all other conditions for importation or exportation have been complied with; in appropriate cases, this time-limit may be extended by another 10 working days. If proceedings leading to a decision on the merits of the case have been initiated, a review, including a right to be heard, shall take place upon request of the defendant with a view to deciding, within a reasonable period, whether these measures shall be modified, revoked or confirmed. Notwithstanding the above, where the suspension of the release of goods is carried out or continued in accordance with a provisional judicial measure, the provisions of paragraph 6 of Article 50 shall apply."</p> |

Summary of Proposals for Amendment

| CURRENT WORDING OF SECTION | PROPOSED AMENDMENTS | REMARKS/JUSTIFICATIONS |
|----------------------------|---------------------|---|
| | | <p data-bbox="1002 296 1225 322">OTHER COMMENTS</p> <p data-bbox="1002 364 1487 873">There are various provisions under the Act that authorize the inspectors/customs officials to act on their own initiative. IP rights are private rights and should rightfully be enforced by a rights holder with valid grounds. Where the right holder of the IP is not interested in pursuing the case the inspectors/customs officials should not be authorized to act suo moto – action taken by the authority without formal complaint by the owner. The Act is about criminal disputes initiated by the Agency. But then Section 26 (2), (4) and (8) refers to civil proceedings. It is unclear which disputes under the act are civil disputes. Further if civil disputes are covered by this legislation then what types of disputes are covered under other IP laws in the country.</p> |





Conclusion and Call to Action

The ACT as drafted endangers the constitutional right to health afforded to the citizens of the Republic of Kenya, and in turn, the right to life, as guaranteed under Articles 26 and 43 of the Constitution respectively. The inclusion of broader forms of IPRs into this Anti-counterfeiting legislation and specifically conflating issues of quality of medicines with issues of intellectual property propagates confusion and will most likely hamper access to medicines in Kenya. Criminalization of patent infringement, in particular will not only adversely impact access to medicines but also the development of the pharmaceutical industry in Kenya. The perception that stronger IPRs protection will ensure that quality medicines enter Kenya's market is extremely misguided. The only way to address the problems of compromised medicines is to find solutions for the actual problems of high prices of medicines and weak regulatory capacity in Kenya.

The High Court in the case of Patricia Asero Ochieng and 2 Others v. the Attorney General & Another Petition No. 409 of 2009 found that certain

provisions of the Anti-Counterfeit ACT threatens access to affordable and essential medicines including generic medicines. The court called upon the state to reconsider the relevant provisions alongside its Constitutional obligations and make appropriate amendments to ensure the rights of persons dependent on generic medicines are not put in jeopardy. The objective of the Anti-Counterfeit Act (No. 13 of 2008) is to prohibit trade in counterfeit goods. It is worth noting that the history of industrial development of the now industrialized countries as well as the secret of the success of the East Asian economies was very much based on "imitation"/ "borrowing of ideas". There is no evidence suggesting that increased intellectual rights protection in developing countries will lead to more opportunities for accessing up-to-date technologies, or that the global rate of innovation will increase.

The Anti-Counterfeit Act makes manufacturing, production, packaging of "substantially similar" products an act of counterfeiting, which is then subjected to criminal penalties. Furthermore, the



Conclusion and Call to Action

border measures and seizure provisions of the ACT not only apply to importing of goods, but also exporting of goods and goods in transit. This means that goods being exported (i.e., locally manufactured goods) could be detained or seized by the customs on its own accord or as a result of a complaint by the IPR holder. The ACT contains TRIPs plus provisions that are disadvantageous to Small and Medium Enterprises (SMEs) and that could be used by the IP holder to put the SMEs in Kenya out of business.

In light of the discussions contained in this booklet, we call upon the relevant policy makers in Kenya to amend the provisions of the Anti-Counterfeit Act and take all necessary measures to ensure access to affordable and essential medicines including generic medicines in compliance with the judgment of the High Court.


Additionally, we urge the government to fully utilize the flexibilities contained in the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) in order to ensure long term availability, accessibility and affordability of quality medicines in Kenya for the full enjoyment of the highest attainable standard of health guaranteed in Article 43(1)a of the Constitution of Kenya, 2010.


Finally, we call for deliberate focus and allocation of resources to strengthen the capacity of the drug regulatory authority; the Kenya Pharmacy and Poisons Board to actively identify and remove substandard and fake drugs from the supply chain in Kenya.





To support our campaign follow us on:

 @A2MKenya

 Generics-Medicines-are-NOT-Counterfeit-Campaign

**Generic Medicines Are
NOT “COUNTERFEIT”**