Regional Network for Equity in Health in East and Southern Africa (EQUINET)

Anti-counterfeiting laws and access to essential medicines in East and Southern Africa

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The countries in eastern and southern Africa and the East African Community are at various stages of enacting laws to address 'counterfeiting'. Substandard, falsified medicines are a problem for public health, and may lack the active ingredients that make them effective, or if they are harmful. Yet counterfeiting and substandard or falsified medicines are not the same thing. Counterfeiting refers specifically to trade mark infringement and is an intellectual property issue. Substandard falsified medicines are a public health issue. , Laws that define counterfeiting so widely as to include generic medicines have greater potential public harm, as they may limit access to medicines. Counterfeiting is an intellectual property issue for trade authorities, subject to public health obligations. But regulation of substandard, falsified medicines is a matter for public health and drug authorities. This policy brief draws policy makers attention to the need to ensure that counterfeit laws do not include generic medicines, and do not take over authority from drug regulators to manage substandard and falsified medicines. .

Key messages

1. People often confuse counterfeit, substandard and generic medicines – using the terms interchangeably. WTO in the TRIPS agreement in Article 51 defines "counterfeit" as trade mark violation. Counterfeit medicines that are deliberately and fraudulently mislabelled with respect to identity and/or source thus violate intellectual property. .
2. Substandard and falsified medicines are those that do not meet quality, safety or efficacy standards and thus pose a health risk to consumers. Controlling substandard, falsified medicine calls for special measures and competencies and should be the responsibility of national drug regulatory agencies.
3. Countries in east and southern Africa are enacting laws against counterfeiting. However many of these laws currently have a wide definition of counterfeits, include generic medicines and would thus obstruct access to these essential low cost medicines in low income countries.
4. In passing anti-counterfeit laws, countries need to define counterfeiting within the limited scope of the TRIPS agreement and separate this from the laws and drug regulatory systems governing substandard and falsified medicines. They should ensure that the definition excludes generic medicines; and preserve their rights to use TRIPS flexibilities.
5. The authority empowered to implement counterfeit law in relation to medicines should be the national drug regulatory authority. The law should provide that the Commissioner of Customs should seek court orders to seize the alleged counterfeit products on the basis of information provided by the aggrieved party or the drug regulatory authority.

What are counterfeits?

The definition of what constitutes counterfeits or counterfeiting is a problematic aspect of anti-counterfeiting laws worldwide (WHO, 2010). People confuse counterfeit, substandard and generic medicines – using the terms interchangeably. But they are very separate issues and clearly defining their differences is critical to any discussion.

Counterfeit medicines are products that are presented in such a way as to look like a legitimate product although they are not that product. In legal terms, this is called trademark infringement. They are the result of deliberate criminal activity.

WHO has defined counterfeit medicine to include medicines that are *"deliberately and fraudulently mislabelled with respect to identity and/or source".* However WHO has also included in the definition products *"with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging."(WHO, 2010).* This is problematic when it mixes pharmaceutical quality and safety with mislabelling.

According to article 51 of the TRIPS Agreement, counterfeit products specifically refer to trade mark violation and this is the only aspect that intellectual property law should address. Issues of medicine quality, safety and efficacy are not matters for intellectual property law as they are separate to counterfeiting. They are therefore issues for laws regulating drug safety.

Generic drugs, are legitimately produced medicines that are the same as the original brand name product. They contain the same active ingredients but are not made by the company that first developed, marketed and often patented the drugs. A generic product is in general not patent-protected but it will have the same effect as the patented brand name product. Because generics are in general a lot cheaper than patented products, they have played a huge role in making sure people actually have access to essential medicines in the Africa and other developing regions, where for instance people overwhelmingly rely on quality generics for its antiretrovirals to treat HIV/AIDS. Generic medicines are produced under the flexibilities provided by the TRIPS Agreement, which prescribes the minimum standards on IPR protection.

The TRIPS Agreement provides in Article 31 that member countries may make national laws that allow them to grant licenses to other producers for the production of a patented medicine if the patent owner cannot provide it at a reasonable price or in sufficient quantities. The agreement also offers authority for government-use order and parallel importation. Normally, these processes facilitate the production or access to generic medicines to improve availability or affordability of essential medicines for public health. Thus generic medicines are not counterfeits and are legitimate and legal.

A substandard product is one that does not meet the standards or quality set by the relevant authority. Substandard products result from failures in quality control in the production or handling of a legal or counterfeit product. According to the WHO, while these are genuine medicines produced by legitimate manufacturers, they do not meet the quality specifications that the producer defines. This may not be an intention to cheat, but may be due to problems with the manufacturing process (WHO, 2005).

What problems do counterfeits pose?

It has been alleged that trade in counterfeits is extremely high and is a growing problem (Grossman and Shapiro, 1988) One World Health Organization (WHO) estimate suggests that about one third of the medicine on sale in Africa is counterfeit (Cockburn, 2005; Progressive Policy Institute, 2007). There is debate on the accuracy of these estimates and the methods used to reach them. It is also noted that some assessments conflate 'counterfeit' with 'substandard' medicines, and use evidence of substandard medicines to raise concern about counterfeits. There are thus no generally agreed estimates of the size of the problem of counterfeit medicines.

Consumption of substandard products poses a public health problem due to safety risks, and substandard, falsified medicines can be dangerous, as they may lack active ingredients. Their use can result in treatment failure or death (WHO, 2010). Substandard medicines may be simple placebos, with no active ingredients; .contain incorrect dosages of the right ingredients, or contain medicines other than those on the label. They may contain high levels of impurities and contaminants (Progressive Policy Institute, 2007; International Pharmaceutical Federation, 2003). This has consequences in morbidity, mortality, and loss of public confidence in medicines and health services.

However it needs to be noted that not all products that infringe trade mark violations are substandard, and not all substandard products infringe trademark violations. The two issues are separate.

How are countries in the region managing counterfeits?

Within the East Africa, national governments and regional authorities are at various stages of enacting policies and laws against counterfeiting. The policies aim to be a basis for a robust legal framework for the protection and enforcement of intellectual property rights in the region that combat counterfeits and pirated products (EAC Draft Policy, 2010).

The East African Community (EAC) secretariat has developed a draft policy and a bill; Uganda is working on a bill; Kenya has already enacted a law; while Tanzania has developed regulations. The East African Community (EAC) draft Policy on Anti-Counterfeiting, Anti-Piracy and Other Intellectual Property Rights Violations states its objective as *"To provide a Policy basis for a robust legal framework for the protection and enforcement of Intellectual Property Rights in the Region with specific focus on combating counterfeits and pirated products." The* draft East African Community Anti-Counterfeit Bill, 2010 aims *"to prohibit trade in counterfeit goods, to establish national anti-counterfeit boards and for connected purposes".*

Why are public health practitioners and civil society concerned about these measures?

There is now mounting concern that the counterfeit laws in the region will obstruct access to essential generic medicines, and thus undermine public health in the region. This arises due to the definitions used of counterfeits.

The current and draft laws in East Africa define counterfeits so broadly to encompass legitimate products, notably generic medicines.. The Uganda bill and the Tanzania regulations refer to the "authority of the owner of any intellectual property right" in respect of the goods protected. This effectively excludes any permission to produce generic essential drugs.

They also exclude the flexibilities provided for in the TRIPS agreement. Article 51 of the TRIPS Agreement restricts counterfeiting to trademarks goods and pirated copyright goods. The proposed laws in the region are not consistent with the TRIPS Agreement, however, as their scope extends to patents and other aspects of IPRs. They ignore the flexibilities that the TRIPS Agreement provide for medicines, including the alternative avenues of authorizing the production of a product, such as compulsory licensing or parallel importation. These flexibilities give generic medicines legal status although they are produced "without the authority of the IPR owner."

The anti-counterfeiting laws or bills have identified agencies that will oversee the implementation of the law. In Kenya, this is a commission, in Uganda, it is the Uganda National Bureau of Standards (UNBS), while in Tanzania an Interdepartmental Task Force does this. This poses a specific challenge when it comes to medicines. A typical standards agency would ordinarily not have the requisite knowledge to deal with counterfeit medicines, a function normally resting with the drug regulatory authorities.

Inspectors of counterfeit products are also appointed by these bodies, and have powers that may lead to abuse, if there is inadequate specification of how an authority satisfies itself that the alleged goods are counterfeits. In Uganda, for example, the Commissioner of Customs is granted wide discretion in determining what a counterfeit product is, without room for the expert regulatory agencies to participate in this determination. Such wide discretions could result into wrongful border measures, as happened in Europe, where EU customs officials seized medicines in transit although there was no evidence of violation of IPR.

Are public resources being used to promote private interests?

Some argue that the counterfeit problem is being taken advantage of by those who seek to ration access to intellectual property (IP). Certainly there has been a to and fro in recent years between those who seek to ration and those who seek to expand access to IP (Sell, 2009). IP protection is important for developed countries. For example, in 2001, more than 50% of USA exports are cited as depended on some form of IP protection (Norton and Schlee, 2002). An International Anti Counterfeiting Coalition (IACC), representing a cross section of businesses and industries has been set up to combat product counterfeiting and piracy (See: http://www.iacc.org/). It does this by promoting laws, regulations and directives designed to raise IP protection to higher levels and render the theft of IP undesirable and unprofitable.

Civil society activists and some governments in low income countries have resisted this increased protection of IP as limiting access to knowledge, technology, educational materials, essential medicines, and other important resources. Some insist that patent issues be separated in law from the trademark and copyright issues that relate to counterfeiting. WHO has also separated patent from counterfeiting issues, noting that both branded and generic medicines have been counterfeited (WHO, 2010).

In some draft laws, such as in Uganda and Kenya, the Commissioner of Customs takes on the time and cost of enforcing the rights of patent holders. This forces the alleged counterfeiter to go to court, rather than the aggrieved patent holder. In an adversarial system as those in East Africa, in a civil action, it is rather the aggrieved party that should seek court decisions. In this regard, the Commissioner of Customs is not the right institution to seize alleged counterfeit goods.

Remedies to counterfeiting that protect access to medicines

We suggest that countries adopt legal and institutional approaches to controlling counterfeiting that do not obstruct access to generic medicines. We also suggest that the laws and their enforcement agencies for intellectual property manage counterfeits in medicines strictly in terms of trade mark violations, and that matters relating to quality, safety and efficacy and thus substandard and falsified medicines are managed by public health and medicine regulatory laws and authorities.

Firstly, the law needs to define counterfeiting more specifically in line with the internationally accepted Article 51 of the TRIPS agreement and ensure that their legal definitions do not include generic medicines or seek to take over public

health authorities for ensuring safety, quality and efficacy. For example, under pressure from civil society activists, the Kenya government added a clause 2 (d) to its law to incorporate the WHO definition of counterfeit as it related to medicines before the law was passed. However confusion remains as the initial clauses drafted remained intact, citing counterfeiting referring to actions done "without the authority of the owner of any IPR subsisting in Kenya or elsewhere…", or prohibiting generic medicines.

The policy and protocol being drafted by the EAC on the Utilisation of Public Health Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation provides for the enactment of anti counterfeiting laws to protect the policy space to use TRIPS Flexibilities.

Secondly the authority empowered to implement law in relation to substandard and falsified medicines should be the national drug regulatory authority. Strengthening the national drug regulatory authorities and pharmacovigilance offers one of the best policy options for dealing with medicines that are substandard or falsified. Hence, for example in Uganda, section 4 of the proposed Bill on counterfeiting should make clear the role of the national drug regulatory authority in dealing with all matters to do with falsified, substandard medicines. Where trade mark infringement affects the good itself, the National Bureau of Standards does not have the capacity to determine the standard of medicines. This should be done by the national drug regulatory authority.

Thirdly, the law should provide that the Commissioner of Customs seek court orders to seize the alleged counterfeit products on the basis of information provided by the aggrieved party or the drug regulatory authority.

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