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. Counterfeiting is a problem for public health if counterfeit medicines lack the active ingredients that make them effective, or if they are harmful. Yet laws that define counterfeiting so widely as to include generic medicines have even greater potential public harm, as they may make these essential medicines available as branded versions, at significantly higher cost. This policy brief draws policy makers attention to the need to ensure that counterfeit laws do not inadvertently include generic medicines. It discusses the key issues in these laws and draft laws and how they are likely to affect public health and access to essential medicines in the region.

Key messages

1. People often confuse counterfeit, substandard and generic medicines – using the terms interchangeably. WHO defines counterfeit medicine as deliberately and fraudulently mislabelled with respect to identity and/or source.
2. Counterfeits pose a health risk to consumers, and counterfeit medicines pose even greater risks. Controlling medicine counterfeiting 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, beyond the WHO definition above, that includes 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 agree on and apply a shared definition within the World Health Assembly; define counterfeiting within the scope of the TRIPS agreement; ensure that the definition excludes generic medicines; and preserve their rights to use all 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 often seem to 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 defines counterfeit medicine as: *"a medicine which is deliberately and fraudulently mislabelled 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."(WHO, 2010)*

The key aspect of the WHO definition is that counterfeiting is a criminal activity, where there is intentional misrepresentation.

Generic drugs, in contrast, 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?

Trade in counterfeits is reaching epidemic proportions. (Grossman and Shapiro, 1988) Some estimates suggest that the world market for counterfeit products could be as high as 10% of world trade. The Organization for Economic Co-operation and Development (OECD) and other international organisations estimates trade in counterfeit goods– excluding domestically produced fakes and digital copyright theft such as illegal downloads – to have reached between US$200 billion and US900 billion, growing by over 10000% in the past two decades (Progressive Policy Institute, 2007). One World Health Organization (WHO) estimate suggests that about one third of the medicine on sale in Africa is counterfeit, while other sources suggest that counterfiet medicines is a problem affecting mostly Africa and Asia(Cockburn, 2005; Progressive Policy Institute, 2007). While there is some debate on the accuracy of these estimates and the methods used to reach them, and no generally agreed estimates exist of the size of the problem, counterfeits have become an issue that has rerached policy attention.

While consumption of counterfeit products poses a public health problem due to safety risks, the problem is particularly grave when the counterfeited goods are medicines, as their content can be dangerous or they may lack active ingredients. Their use can result in treatment failure or death (WHO, 2010).

About 30% of counterfeit medicines are alleged to be simple placebos, with no active ingredients. A fifth are alleged to contain incorrect dosages of the right ingredients, and another fifth to contain medicines other than those on the label. About 8% are observed to contain high levels of impurities and contaminants (Progressive Policy Institute, 2007; International Pharmaceutical Federation, 2003). Where they are used, substandard and fake drugs pose a problem that has consequences in morbidity, mortality, and loss of public confidence in medicines and health services.

How are countries in the region managing counterfeits?

The scale of the trade in counterfeits and its consequences has increasingly attracted international concern and response, including strengthening and enforcing laws against counterfeiting. 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. They do not incorporate the definition proposed by WHO. 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, 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. They 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.

Firstly, the law needs to define counterfeiting more specifically in line with the internationally accepted Article 51 of the TRIPS agreement, as reinforced by the WHO definition, and ensure that theirlegal definitions do not include generic medicines 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 a vital tool so that the enactment of anti counterfeiting laws also protect the policy space to use TRIPS Flexibilities.

Secondly the authority empowered to implement counterfeit law in relation to 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 counterfeiting in medicines. Hence, for example in Uganda, section 4 of the proposed Bill on counterfeiting should be amended to vest the required functions of dealing with counterfeit medicines to the national drug regulatory authority, rather than the National Bureau of Standards.

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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