

TRADE & HIV

Rethinking the role of intellectual property policy in the HIV response in the East Africa Community

Provisions of the Draft Regional Intellectual Property Policy and Protocol on TRIPS Flexibilities and Public Health should be used to improve the anti-counterfeiting legislations being developed by the East African Community (EAC) and its member states. This will, among other things, contribute to region's response to the HIV/AIDS epidemic by promoting and guaranteeing expanded supply and access to safe and efficacious generic antiretroviral medicines

Current HIV/AIDS treatment access challenges in East Africa

As the world celebrates the continuing decline in AIDS deaths, eastern Africa continues to have some of the worst epidemic indicators, as the number of new cases resurge even in countries such as Uganda whose response to the epidemic was previously considered a success story. An estimated 22.5 million people are living with HIV in the Sub-Saharan Africa— around two thirds of the global total.

Globally, the number of new infections and AIDS-related deaths has fallen by nearly 20% (UNAIDS, 2010). Access to affordable and good quality generic medicines has played a key role in this achievement. The use of TRIPS-compliant flexibilities in intellectual property (IP) laws to ensure wide availability of affordable medicines is one of the factors that have positively influenced improvements in access to treatment (UNDP, n.d.)

However, the gap between need and access to medicines still persists. The burden of HIV/AIDS, remains disproportionately high with 60% of those needing antiretroviral therapy still untreated. In its recently revised HIV treatment guidelines the WHO recommend starting ART at a higher CD4 cell count, which means that the number of people who require treatment reached approximately 16 million in 2010. Recent scientific evidence on the role of treatment as/ for prevention, with 96% reduction in the risk of HIV infection in some cases, and the potential use of ARVs for prevention is another reason to predict an even greater increased need of affordable generic ARVs.

In East Africa, adult HIV prevalence exceeds 5% in Uganda, Kenya and Tanzania. There are an estimated 1.2 million people living with HIV in Uganda; a similar

number of adults (15-plus) in Tanzania; and 1.5 million in Kenya. All these people need access to treatment.

Due to lifelong demand, the high costs of originator medicines and the continuing stigma around HIV, there are strong financial incentives for illegal production and trade in “cures” that have no proven therapeutic effect and in substandard and falsified antiretrovirals (Amon, 2007; UNDP, n.d.).

Implications of the anti-counterfeit policy and legislative processes

The East African Community (EAC) and its different individual member states are at different stages of reforming their trade policies and laws, specifically in the field of intellectual property rights (IPRs). At the regional level, the EAC has drafted the EAC Anti-Counterfeit Bill (2010) and the EAC Anti-Counterfeit Policy.

At the level of individual member states, Kenya has enacted the Kenya Anti-Counterfeiting Act of 2008; and Tanzania, the Merchandise Marks Regulations Act of 2008. Uganda has published the Anti-counterfeit Bill of 2011.

The primary justification of the proposed the anti-counterfeit legislations is to improve the “business and investment” climate in the region. The draft EAC policy claims that the basis for the law is the fact that trade in counterfeit and piracy (any good that infringes any IPR) has increased. While trade in counterfeit goods has generally increased for various reasons, the approach of tightening IP protection is the wrong solution.

Anti-counterfeit measures are not an appropriate policy measure for curtailing the spread of substandard and



falsified products, including medicines. The likely impact of the draft EAC law will be huge implementation costs through monitoring and settling international trade disputes; and IPR border controls and criminalizing possession and trade in IPR infringing goods deters overall trade, in both IPR infringing goods and non-infringing goods.

The basic characteristics of the IP-related “anti-counterfeiting” approach to addressing quality, safety and efficacy are:

- Use of the term “counterfeiting” to cover all forms of IP infringement, including civil trademark infringement and patent infringement, as well as TRIPS-defined criminal trademark infringement.
- A focus on criminal IP enforcement and seizures/destruction not only for goods imported and exported but also those in transit.
- Designation of customs officials as drug safety inspectors.
- Designation of health and drug regulatory inspectors as IP-related “anti-counterfeiting” inspectors.
- Adoption of certain pro-IP presumptions regarding the IP basis of rightholders’ claims.
- Disproportionately severe penalties, including long prison terms for “counterfeiters”.

Differentiating generic from counterfeits and substandard medicines

A **generic medicine** is a legitimately produced medicine that is the same as the original brand name product – it contains the same active ingredients but is not made by the company that first developed, marketed and often patented the drug. 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 (Article 31) that member countries may make national laws that allow them to grant licences 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.

Article 51 of the TRIPS Agreement restricts counterfeiting to trademarks and copy rights. Anti-counterfeiting agenda and proposed legislations in the region are not consistent with the TRIPS Agreement, as their scope extends to patents and other aspects of IPRs. As observed by the WHO, counterfeiting can apply to branded medicines as well as generic medicines.

Generic medicines are therefore different from counterfeit medicines and substandard medicines. A **substandard product** is one that does not meet the standards set by the relevant authority. Such a product fails to meet the required or expected quality. Substandard products result from failures in quality control in the production or handling of a legal or counterfeit product.

According to the WHO, substandard medicines are genuine medicines produced by legitimate manufacturers that do not meet the quality specifications that the producer says they meet. For example, they may contain less (or more) active ingredient than written on the package. This may not be an intention to cheat, but may be due to problems with the manufacturing process.¹

According to the WHO, a counterfeit medicine is “One which 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.”

The TRIPS Agreement uses the term “counterfeit” more precisely and uses the related term “counterfeiting” only in the context of criminal trademark infringements that are wilful and on a commercial scale.



The Draft EAC Regional Intellectual Property Policy and Protocol on TRIPS and Public Health

The East African Community (EAC) has drafted a policy and protocol on the Utilisation of Public Health-Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation. The draft policy and protocol aim to guide the EAC Partner States on how their national Intellectual Property (IP) legislation should be adjusted in order to enable them to fully utilise public health-related TRIPS flexibilities for optimising the populations' access to health products and medical devices.

The draft policy provides the "road map" by outlining the public health-related TRIPS flexibilities; analyses national IP legislation and identifies areas where TRIPS flexibilities have not been considered to the fullest yet; and provides policy recommendations as to the implementation of TRIPS flexibilities to the fullest extent. The protocol on the other hand provides guidelines to EAC countries on the use of flexibilities.

Public health-related TRIPS flexibilities in the EAC public health policy/protocol

All the EAC member states are members of the World Trade Organisation (WTO) and have an obligation to give effect to the TRIPS Agreement. Like any other WTO member, EAC countries may, but are not be obliged to, implement in their law more extensive protection than is required by WTO-TRIPS, provided that such protection does not contravene the provisions of the TRIPS Agreement. They are free to determine the appropriate method of implementing the provisions of Agreement within their own legal system and practice.

They are also free to utilise a set of provisions – better known as flexibilities – intended to promote public health:

- No patents on pharmaceuticals/ non-enforcement of pharmaceutical patents until 2016 (transition period for LDCs)
- Patent oppositions
- Limit the scope of future patents No patents on natural substances/traditional medicines
- No patents on new medical uses
- No patents on minor structural changes
- Strict application of patentability criteria
- Sufficiently Clear Disclosure requirement
- Allow researchers to use patented substances (research exception)
- Allow generic pharmaceutical producers to use

patented substances for marketing approval applications (Bolar exception)

- Allow third parties to import pharmaceuticals, without the consent of the right holder, from countries where they are sold at prices lower than in the home country (parallel importation)
- Authorise the government or third parties to use patented substances without the consent of the patent right holder and use this flexibility to the fullest (compulsory licensing/ government use)
- Provide for compulsory licensing where patent right holders abuse their rights
- Control anti-competitive behaviour (e.g. prohibitive terms in licensing agreements)
- Allow DRAs to rely on originator test data when granting marketing authorisation for generic drugs and grant marketing authorisation without considering the drug's patent status

Conclusion

The most critical threshold issue for public health in any "anti-counterfeit" legislation is limiting the scope of the activities and conduct that is criminalized to what is prescribed by the TRIPS Agreement. There is need to develop an alternative, positive, public health-driven agenda for improving access to safe and efficacious medicines of assured quality. There is a critical need to find legislative and policy approaches that would reduce the spread of such illicit, unregistered, and unsafe products without hindering access to good quality, safe and efficacious medicines - particularly legitimate and affordable generics of assured quality.



References

(Endnotes)

- 1 http://www.wpro.who.int/media_centre/factsheets/fs_20050506.htm

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