



Regional Dialogue: Africa

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FACT SHEET: Intellectual Property Rights and Access to Medicines

23 million of the 33.3 million global HIV infections have occurred in Africa. The availability of quality and affordable generic medicines, the increases in donor funding, investments in health systems, and the use of flexibilities in intellectual property laws have resulted in a more than 20-fold increase in access to ARVs over the past ten years. However, the demand for treatment persists and remains unmet. Currently around 10 million people need treatment but are unable to access it. Recent scientific evidence on the role of treatment as prevention, with 96% reduction in the risk of HIV infection in some cases, is another reason to encourage the scale up of treatment.

According to the UNAIDS outlook on the future of treatment, it is important to address cost as a treatment obstacle. Treatment 2.0 indicates that prices of medicines and testing account for approximately 40% of the treatment cost. This makes it important for countries to have in place intellectual property rights protection norms that consider public health obligations and allow the supply of affordable generics. The WTO TRIPS Agreement contains flexibilities which have been reaffirmed by the Doha Declaration. Under the TRIPS IP regime, LDCs enjoy special waivers. Unfortunately, many national IP laws in African countries do not include these flexibilities and have adopted regimes that exceed the requirements under the TRIPS Agreement. There are also tendencies to increase IP enforcement through the so called “anti-counterfeit” initiatives: regionally, for example in the East African Community (EAC) and domestically, with Member States of the EAC and in other African countries. These initiatives are led by the legitimate concern about substandard, spurious and falsified medicines. However, the legislation in its current form could hamper access to generic medicines. Lastly, many TRIPS-plus regimes could be adopted through free trade agreements such as the Economic Partnership Agreement between the European Union and the Southern African Development Community. There is a need for comprehensive efforts to ensure public health friendly IP regimes in Africa.

Patent laws

Status Update:

- 42 of the 53 African states are members of the WTO and must comply with its rules, including the TRIPS Agreement. This said, countries can use public health related TRIPS flexibilities to reduce medicine prices. Also, all LDCs in Africa remain exempt from having to comply with TRIPS until July 2013, and from granting pharmaceutical patents until January 2016.

Challenges:

- *Developing Domestic legal frameworks do not sufficiently make full use of TRIPS flexibilities.* Several countries including Madagascar, Lesotho, Nigeria, Tanzania and Uganda all have legal frameworks which pre-date TRIPS. There is a need to develop new laws that incorporate the TRIPS public health flexibilities to enable better access to medicines.
- *Advocating for the greater use of the WTO waiver for least developed countries.* At least half of the African states who are members of the WTO are eligible to apply for the WTO waiver regarding the implementation of TRIPS in respect of pharmaceuticals, but very few have used this strategy to reduce the cost of medicines.

- *Developing a framework for local patent examination.* Very few countries, including Egypt, Kenya and Zambia, have a system of substantive patent examination. Other countries have their patent applications examined by regional bodies, such as the Africa Regional Industrial Property Organization (ARIPO) and Organisation Africaine de la Propriété Intellectuelle (OAPI) but the problem with the lack of examination or lax systems is that almost any claimed invention can be patented, keeping generic competition out for longer periods.

Patent Standards

Progress

- Most of countries which are TRIPS-compliant require the patent application to meet the criteria of novelty, inventive step and industrial applicability.

Challenges

- *Advocating for countries to use the TRIPS flexibility to define the criteria of novelty, inventive step and industrial applicability in the examination of pharmaceutical patents.* Domestic legislation should not allow the granting of patents unless the innovation is genuine, thus preventing frivolous patents and the problem of ‘ever-greening.’ Also, the list of exclusions from patentability should be expanded to include, for instance, new uses of known medicines or new dosages and formulations.

Parallel importation of medicines

Progress:

- Some countries allow for the parallel importation of drugs, Kenya being the most progressive example of this.

Challenges:

- Very few countries have adopted the principle of international exhaustion of IP rights, a principle which permits parallel importation of patented products from anywhere in the world. Many countries still retain the principle of national exhaustion of rights which prevents parallel importation altogether.

Compulsory licences

Progress:

- Most African countries have legislation allowing for compulsory licences to be issued in one form or another. Compulsory licenses have only been used by a minority of countries in sub-Saharan Africa to reduce the cost of treatment. These include the issuing of a government use orders in Zimbabwe in 2003, Mozambique and Zambia in 2004, as well as the use of the August 30th agreement by Rwanda in 2007 to import medicines produced under compulsory license in Canada.

Challenges:

- Although most countries have compulsory license provisions, compulsory licensing and government use orders remain underused, considering the public health need. Some compulsory licensing provisions are complicated and difficult to use, and can be further slowed down by directing disputes to the courts rather than to an administrative or quasi judicial body which could settle issues quickly and prevent unnecessary delays.

Other flexibilities contained in the TRIPS Agreement

Progress:

- There has been some use of TRIPS flexibilities in addition to compulsory licensing. For instance, treatment activists in South Africa used competition law in 2002, 2005 and 2007 to reduce the price of medicines.

Challenges:

- Greater incorporation of the early working flexibility into intellectual property legislation is required as it has not been included in the law of several countries. This provision allows a generic competitor to start the process of bringing its product to market before the expiry of the patent, so that upon expiry, the generic will have been registered for use by the drug regulator.

Prohibiting counterfeiting without undermining access to generic drugs

Progress:

- A number of countries in East Africa, the East African Community itself, such as Kenya and Uganda as well as other African countries like Malawi, have either adopted, or are reportedly considering “anti-counterfeit” legislation with the aim of curtailing the spread substandard or falsified medicines.

Challenges:

- Ensuring that counterfeit legislation doesn't undermine access to generic medicines.* In 2010, Kenya's anti-counterfeit act was successfully challenged in national courts by people living with HIV as including generics in the scope of “counterfeits” thereby violating the people's constitutional right to life. Uganda has since amended the definition in its draft law. National drafts, as well as the regional draft policy and bill suffer from numerous terminology and structural problems but the bigger question is whether they are needed at all. Due to broad definitions of the term ‘counterfeit’ “anti-counterfeit” laws could undermine access to generic medicines, which has been proven. There is no evidence that “anti-counterfeit” measures prevent or limit the spread of substandard or spurious medicines.

Primary Sources

- UNDP, 2010, Good Practice Guide: Improving Access to Medicines by Utilizing Public Health Flexibilities in the WTO TRIPS Agreement
- UNDP, UNAIDS and WHO, 2011, Joint Policy Brief: Using TRIPS Flexibilities to Improve Access to HIV Treatment
- UNDP, OSI, HAI-Africa, 2010, The Proliferation of Anti-counterfeiting Legislation in the East African Community: Addressing Public Health, Copyright and Developmental Concerns
- UNAIDS. 2010, Treatment 2.0: Is This the Future of Treatment. 2010,
- UNAIDS, 2010. *UNAIDS Report on the global AIDS epidemic*, Geneva, Switzerland.
- UNAIDS, 2011. *AIDS at 30: Nations at the crossroads*. Geneva, Switzerland. New York USA available from http://www.unaids.org/en/media/unaids/contentassets/documents/pressrelease/2011/06/20110603_PR_AIDS_30_en.pdf.

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