The Global Commission on HIV and the Law: Access to Essential Medicines

HIV and the Law: Risks, Rights and Health **is a July 2012 report by the Global Commission on HIV and the Law. The Commission was an independent body of experts and respected statespersons established by United Nations Development Programme to address the ways in which human rights abuses, stigma, and discrimination fuel the global HIV epidemic. The Commission set out to examine where and how these abuses were occurring and to consider how legal reforms—through new legislation, better enforcement of existing law, and court decisions—could slow the spread of HIV and reduce its impact.**

The Commission conducted an eighteen month process of research, consultation, analysis, discussion, and decision-making. They held regional dialogues in seven global regions and collected **written and oral submissions from over 1000 individuals and organizations**, more than 700 of whom included people living with, or directly affected by HIV and AIDS.

The report is an important tool for civil society groups, particularly those working with populations at high risk of HIV. This briefing paper highlights the report's findings about access to essential medicines. It offers information and language that may be useful for advocacy, campaigning, and lobbying.

OPEN SOCIETY FOUNDATIONS

Key Report Findings Regarding Access to Essential Medicines

Generic competition leading to a dramatic decrease in the price of antiretroviral (ARV) drugs was a critical factor in the massive scale up of AIDS treatment in developing countries.

- Thanks in large part to increased competition from generic drugs, "the prices of first-generation ARVs have fallen dramatically over the past ten years" (page 76). This has lowered the rate of HIV-related death and illness by making these medications more widely available in low and middle-income countries.

A large treatment gap remains. Many still don't have access to the best available 1st line treatment, and an growing numbers of people need 2nd or 3rd line treatments, which remain expensive. For newer and better drugs, intellectual property (IP) protections on pharmaceutical products and monopoly pricing impede access.

- In the past, countries had the freedom to decide what was patentable within their borders. This kept the quest for profitability from interfering with other public policy goals and considerations—such as the delivery of health care. But this has changed. The multilateral *Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)*, signed in 1994 and administered by the World Trade Organization (WTO) member states, requires countries to set "minimum standards for protecting and imposing IP rights to an extent previously unseen at the global level" (page 80).

  Under TRIPS, all WTO member countries are required to grant patent protection for a minimum of 20 years "in all fields of technology including pharmaceuticals, without distinction based on place of invention or country of manufacture" (page 80). The stated purpose of this is a strong financial incentive to develop new pharmaceutical products and balance the patent holders' right to make money against the right of consumers to access the products they need. But the balance has tipped dangerously to benefit the pharmaceutical companies. The real result is the creation of international "legally protected monopolies" (page 80) that make many patented ARVs unaffordable to those in low and middle-income countries.

A number of trade and investment agreements are incorporating even more stringent IP provisions, posing a serious threat to access to medicines.

- "Recent bilateral and multi-lateral trade agreements have undoubtedly increased the power of pharmaceutical patent holders to control the price of drugs on global markets. Governments, especially in low and middle-income countries, cannot afford them" (page 77). The US and the European Union are aggressively promoting ever stronger IP provisions that reduce countries' ability to regulate medicines pricing or promote their own production and distribution of generics (page 83). If the developing countries refuse to accept such terms, they are denied the right to export their goods to developed country markets (page 83).

Multinational pharmaceutical companies and pharma-friendly governments have promoted anti-counterfeiting trade agreements and legislation that inaccurately conflate counterfeit and poor quality drugs with generics.

- Such regulations imply that the generics are also "substandard formulations that endanger people who take them," (page 82) and that they are inferior to brand name medicines. Drug quality, safety and efficacy issues have nothing to do with IP and need to be addressed by the appropriate drug regulatory authorities rather than under anti-counterfeiting laws.

There are internationally accepted legal "flexibilities" that allow countries to adopt and interpret IP rules to protect public health and access to medicines.

- The 2001 *Doha Declaration on TRIPS and Public Health* says that WTO member countries have the right to use specific "flexibilities" and other provisions in TRIPS to achieve the goal of making medicines accessible for all (page 80). One of these is the "government use" provision which allows a government to either import or locally manufacture generic versions of a patented drug for "public non-commercial use." Another is the "compulsory license" provision which allows a government to impose a license for generic production by another producer—in return for royalties—if their negotiations with the patent holder for a voluntary license have repeatedly failed. Between 1995 and 2011, 17 countries used compulsory licenses to increase access to medicines.

  Using these flexibilities, however, can be complicated and has been "met with retaliation and opposition from some high-income countries and corporations" (page 81). After issuing several compulsory licenses, Thailand was placed on the United States Special 301 Priority Watch List—a list of countries judged to have violated trade agreements—despite having "scrupulously followed TRIPS requirements and national law"(page 81) throughout the process.

Drug development should also be promoted outside of the patent system.

- "For diseases affecting millions of poor people in developing countries, patents are not a relevant factor or effective in stimulating [research and development] and bringing new products to the market." (page 85). Several proposals to move away from a patent-based incentive system to generate innovation include "**innovation prize funds** ... and **open source drug discovery**."

Actions the Report Recommends (page 86)

To create an effective, sustainable responses that support human rights obligations:

- The UN must develop a new IP regime for pharmaceutical products that supports human rights law and public health requirements while safeguarding justifiable profits for the inventors. The body creating this regime must be broadly representative and take current efforts to resolve policy in this area, fully into account. The WTO must suspend TRIPS as it relates to medicines for low and middle-income countries.

- Until the TRIPS provisions regarding access to essential pharmaceutical products are suspended, low and middle-income countries should use the TRIPS flexibilities as broadly and simply as they can. When possible, countries should collaborate and share technical expertise to facilitate full use of the TRIPS exceptions and resist political pressure to abandon such action.

- High income countries must stop pressuring low and middle-income countries to adopt trade agreements that impede their access to ARVs and other life-saving medications. They must cease retaliation against countries using available policy options to resist such impediments.

- A global moratorium must be observed by all countries on inclusion of any IP provisions in any treaty that could limit a country's ability to reduce the cost of—or improve their access to—HIV-related treatment.

- The Anti-Counterfeiting Trade Agreement must be revised to exclude IP provisions or countries must refuse to sign it. Countries must also resist adoption of anti-counterfeiting legislation that inaccurate conflates counterfeit and other substandard products with generics, which limits access to low-cost generics that meet regulatory standards.

- WTO member states must indefinitely extend the exemption for the least developed countries from the application of TRIPS provisions with regard to pharmaceuticals.

- WTO members must refuse to ratify the revisions made to the UN General Counsel's August 30, 2003 Decision, which tried to address drugs export limitations imposed by TRIPS. It has not been a viable solution for countries with insufficient pharmaceutical manufacturing capacity. They should demand instead that the system as described in the Decision be replaced with a mechanism that allows easier importation of pharmaceuticals produced under compulsory license.

- Countries must develop a new pharmaceutical R&D treaty, and promote open source discovery. TRIPSs failed to encourage and reward the kind of innovation to make available life-saving drugs to the poor.

- WTO members must recognize that the TRIPS agreement is dysfunctional in the area of access to essential pharmaceutical products and, in fact, mandates human rights law violations.

How You Can Use the Report

This report provides concrete precedents and examples you can use as evidence when advocating to government and other influential organizations, the media, civil society organizations, and the general public. Because of the report's legitimacy as an official UN document, these case studies and the statements made about them are important tools to support your advocacy, campaigning, and lobbying.

1. **Do some research to find out if your government has the necessary legislative provisions in place to use the TRIPS flexibilities and if it is using them. If it is not, advocate for legislative change and promote their use.**

   Allies with public health legal expertise, parliamentarians concerned about HIV and AIDS (and their staff), and United Nations Development Programme, World Health Organization, or UNAIDS experts should be able to assist with this research and advocacy.

2. **Educate your government about how overly strong IP rules restrict access to medicines using evidence presented in this report, and fight efforts to introduce TRIPS-plus IP laws, including through trade agreements or anti-counterfeiting initiatives.**

   The Brazilian government passed a law in 1996 "guaranteeing affordable access to HIV treatment" (page 76). Based on this, Brazilian NGOs formed a **Working Group on Intellectual Property** and pushed the government to use the TRIPS flexibilities to uphold its commitment.

3. **Go to court to demand that your government provide adequate supplies of ARVs if it has legal or constitutional language guaranteeing medical treatment for citizens.**

   In some countries, because the national constitution stipulates the right to health, governments are obliged to assure citizens' access to ARVs (page 76). "Such legal strategies, together with global advocacy and generic competition, resulted in a 22-fold increase in ART access between 2001 and 2010" (page 76).

4. **Use the available evidence of challenges and successes to build awareness and mobilize advocates for access to medicines.**

   Point to the chart on page 81 to show that compulsory licensing has been a successful strategy in several counties. The chart on page 83 shows the increase in the number of trade agreements containing IP clauses in recent years.

5. **Engage your government and the scientific community in discussions on alternative models for research and development, and promote non-patent incentives.**

"Sound Bite" Quotes

One benefit of this report is that it simply and eloquently frames key arguments we make as we advocate for change in existing policies. These are listed below as sound bites that organizations can use in their own documents or when talking to the media. Citing the Global Commission on HIV and the Law may add credibility for audiences who are less receptive to such arguments.

- "Limited competition resulted in higher costs of medicines. When the product is a pharmaceutical, the outcome for poor countries with overwhelming HIV epidemics and other health challenges has been catastrophic" (page 80).
- "Despite international pressures to prioritise trade over public health, some governments and civil socirty groups are using the law to ensure access to affordable medicines, while exploring new incentives for medical research and development" (page 9).
- "The cost of HIV prevention and care is modest, especially in comparison to the billions spent on bank bailouts or weaponry. If the global community is serious about ending the epidemic, it must spend what is required" (page 76).
- "The crisis of access to medicines is not just a technical problem. It is an issue of laws and politics" (page 85).

Open Society Public Health Program

The Public Health Program of the Open Society Foundations aims to build societies committed to inclusion, human rights, and justice, in which health-related laws, policies, and practices reflect these values and are based on evidence. The program works to advance the health and human rights of marginalized people by building the capacity of civil society leaders and organizations, and by advocating for greater accountability and transparency in health policy and practice. For more information, see: www.opensocietyfoundations.org.