Access to medicines

A briefing paper for the Trade Campaign and the HIV and AIDS Campaign

Access to Medicines

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Access to medicines

Today, at the beginning of the twenty-first century, one in three people in the world are unable to get essential medicines. In the poorest parts of Africa and Asia, this rises to one in two people.

When it comes to medicines to treat HIV and AIDS, the statistics are even more damning. More than five out of six people who need anti-retrovirals (ARVs) do not have access to them – that is 5.5 million people.[1]

People's access to medicines is affected by many things including capacities of health systems and budgets, levels of training and skill of health professionals, and levels of research and development. One important factor is that many medicines are simply too expensive for people to afford. This briefing focuses on the impact of the trade rules in the TRIPS Agreement on the price of drugs.

> Access to medicines is an issue that cuts across campaigning on both HIV and AIDS and on global trade for EAA participants. It is a basic component of the response that is needed to the HIV pandemic, both in terms of anti-retrovirals (ARVs) to treat HIV and basic medicines to treat opportunistic infections. And it is a very real and visible area in which trade rules have a drastic effect on everyday life.

The right to health

Access to medicines is a component of the right to health, a right that is firmly established in binding international law.[2] Under this right, everyone is entitled to access to:

- essential medicines;
- a system of health protection; and
- a range of other goods, services and facilities that enable people to enjoy the highest possible level of health.[3]

It is recognized that the right to health is subject to the realities of limited resources, but this does not mean that it is an empty, indefinitely postponed right. Governments have an immediate and ongoing duty to take any steps they can toward achieving the right to health for all. They most certainly have an obligation not to take any backward steps.

> **Essential medicines** are defined as those that satisfy the priority health care needs of the population. The World Health Organization (WHO) maintains a list of essential medicines.
>
> For more information see http://www.who.int/medicines/services/essmedicines_def/

HIV and medicines

If left untreated HIV is inevitably fatal within 7-20 years in 99% of cases. However HIV is a condition that can be medically managed. The progression of HIV to AIDS can be slowed by improved access to basic nutrition and health care services. Drugs are available to treat common opportunistic infections to which advanced HIV infection makes people vulnerable. And anti-retroviral therapy can stop the replication of the HI virus, restore a person's strength

and vitality and avert death as a result of AIDS. When people have access to ARVs, mortality from AIDS has been reduced by almost 90 percent.[4]

How do trade rules affect the price of medicines?

The price of medicines is affected by trade rules on patents. Patents are part of intellectual property law, which seeks to deal with design, creativity and invention. Other intellectual property tools include copyright and trademarks. Intellectual property is increasingly important for the high-tech 'knowledge economies' of developed countries.

A patent gives an inventor a monopoly on their invention for a set number of years. Others may only produce the invented product or use the invented process if they obtain a license from the patent holder. By preventing competition the patent system allows the patent holder to charge a higher price for their invention.

Patents, pharmaceutical companies and research

Research-based pharmaceutical companies argue that they need patents to allow them to recoup the time and expense involved in researching and developing a drug, and that patents are needed to encourage innovation. However there are limitations to this argument.

The amount that pharmaceutical companies spend on research is much contested. It is also clear that around half of worldwide research and development (R&D) expenditure is publicly funded.[5] Pharmaceutical companies spend more on marketing, advertising and administration than they do on research.[6]

A basic problem with the research cost argument is that in reality pharmaceutical companies recoup almost all of their expenditure in developed countries.[7] This is their main market and their primary focus. Pharmaceutical companies need to have patents in North America, Europe and Japan. The reason they want to have patents in developing countries is primarily to ensure that no one can manufacture drugs cheaply in these countries for sale in profitable markets. The fact that patent protection in developing countries keeps drugs unaffordable for the majority of the world's population is, by this view, a regrettable but unavoidable side effect. This is one of the most blatant cases of putting profits before people.

The patent system, as it is currently structured, encourages the development of lucrative drugs and has no mechanism to support development of medicines for people who cannot pay.[8] The research cost argument has some validity, but it needs to be balanced against public health needs.

What is TRIPS?

Although intellectual property has been the concern of the World Intellectual Property Organization (WIPO) and its predecessor since 1893, until recently intellectual property laws, including patent laws, were a matter for national legislation. Countries were allowed systems suited to their industrial capabilities; some had none. However transnational corporations, especially pharmaceutical companies, lobbied hard for intellectual property to be included in the remit of the World Trade Organization (WTO) in order to establish global intellectual property rules which would be binding on all WTO member countries.

The result of the transnational companies' lobbying was that when the WTO came into being in 1995, intellectual property was one of the three broad areas of trade that are the organization's basis (the others are goods and services). One agreement covers all of the WTO's rules on intellectual property: TRIPS or the *Agreement on Trade Related Aspects of*

Intellectual Property Rights.

TRIPS raised the level of intellectual property protection that countries must provide, setting minimum standards and making this subject to the WTO's dispute resolution system – one of the few multilateral enforcement mechanisms with teeth. The phase-in periods for countries to conform to TRIPS requirements have now (2006) passed, except for the 32 'least-developed countries' (LDCs) who are WTO members. Their transition period extends until 2016 for pharmaceutical products.

Under TRIPS, patents must last for a minimum 20 years, and it became compulsory for medicines to be included under patent protection.

How has TRIPS affected access to treatment for HIV?

The introduction or enhancement of patent protection for medicines through TRIPS has in many cases led to high prices for medicines, making them unaffordable for many people. Many pharmaceutical companies practice differential pricing, charging less for a drug in a developing country than a developed country, but inevitably in a monopoly situation it is likely that the price set will be aimed at maximizing the income of the seller. Although the price may be lower than in some other countries, it may be neither affordable for many in that country, nor as low as it could be.

This has been very apparent when generic competition has been introduced. For instance, at the beginning of 2000 the lowest world price for a year's supply of one anti-retroviral (ARV) triple-therapy[9] to treat HIV and AIDS was $10,439 in the absence of generic competition. When generic competitors appeared on the scene that year with prices as low as $800, the patent holder dropped its price to $931 – a 91% cut. Since then the price of the proprietary drug has continued to fall in response to generic competition, and in June 2005 the price was $562.[10]

The first line of ARV therapy is the older drugs.[11] However after a few years, many patients develop resistance to these, and need to switch to newer 'second-line' drugs.[12] Generic competition, alongside campaigning and increased public awareness has won significant decreases in prices for first-line ARV therapy. However second-line drugs are still priced as luxuries and because of TRIPS, generic competition cannot be used in the same way to lower the price. The first-line drugs were mainly developed before TRIPS came into effect, and there were no patents on them in some key generic manufacturing countries. However second-line drugs fall under the 20 year patent protection of TRIPS.[13]

> Another case that illustrates how voluntary differential pricing by pharmaceutical companies is geared more to profit rather than genuine affordability, is the prices charged for one brand drug, Zantac, in the late 90s. It was sold at:
>
> $2 in India
>
> where it faced generic competition, but without competition it was sold at
>
> $9 in Bangladesh
> $30 in Vietnam
> $37 in Thailand
> $55 in Malaysia
> $61 in Sri Lanka
> $63 in Philippines
> $97 in Tanzania
> $183 in Mongolia
> $196 in Chile
> $132 in El Salvador and
> $150 in South Africa.
>
> Meanwhile, it was also sold at $23 in Australia and $77 in Canada.
>
> Khor, "Intellectual property, competition and development" TWN, June 2005

The '3 by 5' initiative of the WHO and UNAIDS trebled the number of people being treated with ARVs in Africa and Asia. However the gains that the initiative achieved are in danger of being lost if it is not possible for these people to move on to second-line drugs as they develop resistance to first-line ones.

Drugs may simply not be available in a developing country because the patent holder has chosen not to market them where there is little opportunity for profit. For instance, Médecins Sans Frontières (MSF) has been running HIV and AIDS treatment and care projects in China since 2003 but is unable to use a regime of second-line drugs in the programme because patent holders have chosen not to market the drugs in China.[14]

Paediatric medicines are a particular case.[15] Children need different formulations of ARV drugs, and patent holders are charging ten times more for these compared to adult formulations. Again, compared to adult formulations, paediatric drugs are marketed in even fewer countries.

In patent protection, a balance is always needed between the rights of the patent holder on the one hand and public interest on the other. Medicines are not just another product, like a computer chip or a bottle opener; they are often literally life or death. TRIPS has swung the balance too far in favor of the corporate interest of pharmaceutical companies and away from the needs of poor people across the world.

How has the WTO sought to respond to health concerns?

The TRIPS Agreement does state that it "should not prevent members from taking measures to protect public health" but concern over the way TRIPS was being implemented and its negative impacts grew in the years following 1995. In 2001 at the WTO's Ministerial Conference in Doha, this concern led to the 'Doha Declaration' which reaffirmed that:

> "..the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted

Indian generic drugs have, until now, been key in making ARVs available at affordable prices, enabling hundreds of thousands of people to be treated who would not otherwise have been able to afford it. Generic manufacturers in India have also been able to produce fixed-dose combinations of ARVs, a simplification which has been crucial in scaling up treatment programmes in developing countries. Currently around half of the people in developing countries who are on ARVs are taking Indian generic drugs.

Before TRIPS, patents on medicines and food in India were restricted to processes rather than end-products. This made it legal to manufacture generic versions of drugs that were patented in other countries so long as a different process was used. As a result India built up a great expertise in reverse engineering and an extremely efficient generic pharmaceutical sector, becoming one of the main sources of generic drugs in the world.

However in 2005 India changed its laws to comply with TRIPS, and at the beginning of 2006 granted its first patent on a medicine to Roche for a hepatitis C treatment.

For existing drugs the new law does have a system of 'automatic licensing' so that if a patent is now granted in India for a drug that generic manufacturers already make, they will be able to continue making it on payment of a fee to the patent holder, although the level of such a royalty fee has not been defined. Usually the norm is around 3-4% but in South Africa Glaxo Smith Kline attempted to charge 40% until public pressure and the courts intervened.

For new drugs there is no such system of automatic licensing and the system for the government to issue a compulsory license is extremely complex. Indian generic drugs are unlikely to be able to play the same role in making the new second line ARVs more widely accessible as they did with first line ARVs. The Indian generic manufacturing system has a strong enough base to be likely to survive, but its prices will almost certainly rise steeply, and it is likely to focus more on affluent markets, including exporting to the US.

and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose…"[16]

The particular flexibility which the declaration highlighted was the ability of a government to grant a compulsory license. Through a compulsory license the government requires a patent holder to give others a license, although the patent holder has to be compensated. Compulsory licenses are widely used, often to rectify anti-competitive practices. In this case the motivation would be to protect public health, and this need not be limited to an emergency or crisis situation. A compulsory license on a patented medicine enables another pharmaceutical manufacturer to produce a copy, or 'generic' version, of the drug, with the assumption that the increased competition will cause the price to fall.

Some developing countries, notably India, China, Egypt and Brazil, have strong generic pharmaceutical manufacturing sectors. However, many countries lack the capacity and expertise to manufacture generic drugs to high quality standards. A compulsory license in a country only allows medicines to be made predominantly for national use, so as not to undercut international trade. The Doha Declaration therefore recognized that countries without generic manufacturing ability will not be able to make much use of the flexibility available in TRIPS. The declaration called for a solution to be found for this problem by the end of 2002.

It was 30 August 2003 however before even a temporary solution was found, setting up a system whereby importing countries can declare their needs and exporting countries can supply them, under the supervision of the WTO's Council for TRIPS. This agreement was wrapped in burdensome bureaucracy and red tape, and there has been much controversy over interpreting its provisions. Worse, it has simply proved unworkable in practice. No country has been able to make use of it to actually import or export any medicines. No patient has benefited from the '30th August Decision'.

The temporary 30th August Decision had no cut off point. It could therefore have remained in place indefinitely until it was demonstrated to be workable, or a better solution was found. However on 6 December 2005, with the WTO under intense political pressure to produce some kind of success in the days before its lackluster Ministerial Conference in Hong Kong, the decision was made to make the temporary solution permanent. This was trumpeted as a breakthrough for development. It was nothing of the kind. It preserved an agreement that has so far been useless and closed the door on hopes of finding something useful.

Is TRIPS the only game in town?

While the WTO is the only global forum for trade agreements, there are around 300 bilateral trade agreements between individual countries. These agreements can include what are known as 'TRIPS Plus' provisions – provisions that go beyond what is required in TRIPS and that remove the flexibilities that TRIPS provides. These include:

- extending the life span of patents to more than 20 years;
- introducing minor modifications allowing known products to be patented all over again for 'new use', thus further extending the life span of the patent;
- restricting the use of compulsory licenses;
- linking the registration of drugs for use in a country, which is a safety and quality control measure, to patent status; and
- introducing a five-year time span in which generic manufacturers cannot use the test data of the proprietary product to register, although a generic drug is identical to the proprietary drug. This is referred to as data exclusivity.

In its bilateral agreements the US routinely demands TRIPS Plus intellectual property provisions in exchange for what it is offering in access to the US market. Recently these have been included in the US-Peru Free Trade Agreement (FTA), the Central American Free Trade Agreement (CAFTA), the US-Singapore FTA, the US-Chile FTA, the US-Australia FTA and the US-Morocco FTA. They are likely to be included in agreements that the US is still negotiating with Andean countries, Thailand, Panama, the Southern African Customs Union, Malaysia and South Korea. The EU has not currently included TRIPS Plus provisions in its negotiations outside of the WTO. However there are concerns that it may seek provisions on data exclusivity in the Economic Partnership Agreements (EPA) currently being negotiated with African, Caribbean and Pacific (ACP) countries and in negotiations with India and parts of Latin America.

Within the WTO itself TRIPS Plus provisions have been required of countries that have joined the WTO in the last few years. There is also great international political pressure for countries simply not to take advantage of the flexibilities that are available to them within TRIPS.

In the World Intellectual Property Organization (WIPO), discussion is underway on a new agreement that would go beyond TRIPS, the Substantive Patent Law Treaty (SPLT). This would establish more global standards on what a patent is and how patent systems should be run, which would further reduce the flexibilities available to developing countries.

On the positive side, there have recently been initiatives from developing countries to improve access to medicines. Latin American countries met in January 2006 to discuss working together to manufacture drugs locally. And in the World Health Organization (WHO) Brazil and Kenya have raised the debate on alternative frameworks for financing that could support research and development of drugs while enabling a better balance between intellectual property rights and public health.

What can I do?

Campaign for your government to:

- make full use of the flexibilities available in the TRIPS Agreement
- join the movement to find alternative frameworks for supporting research in medicine that achieve a better balance between intellectual property rights and public health

In particular urge your government to:

- issue compulsory licenses for essential medicines (including medicines to treat HIV and AIDS) when there are problems of access to these medicines due to patent restrictions

Call upon your government NOT to:

- enter into TRIPS Plus agreements
- impose TRIPS Plus agreements on other countries

The EAA is beginning to develop case studies on the impact of trade agreements on access to medicines. If you know of examples, please tell us about them – email info@e-alliance.ch

[1] UNAIDS & WHO, Progress on global access to antiretroviral therapy: an update on '3 by 5'. Geneva: UNAIDS, June 2005, p. 13

[2] Including in the *International Covenant on Economic, Social and Cultural Rights* (article 12), the *Universal Declaration of Human Rights* (article 25.1), the *International Covenant on Civil and Political Rights* (article 6) and the *Convention on the Rights of the Child* (articles 6 and 24).

[3] UNCHR, *The right of everyone to the enjoyment of the highest attainable standard of physical and mental health: report of the special rapporteur, Paul Hunt: addendum, Mission to the World Trade Organization*. UN Economic and Social Council, March 2004. E/CN.4/2004/49/Add.1

[4] A. Mocroft et al, 'Decline in AIDS and death rates in the EuroSIDA study: an observational study'. The Lancet, vol. 362 Issue 9377 p. 22

[5] Médecins Sans Frontières, "Frequently asked questions", http://www.accessmed-msf.org/campaign/faq.shtm No 28: How much does it cost to research and develop a new drug?

[6] Families USA. Off the charts: pay, profits and spending by drug companies. Washington, DC: Families USA, 2001

[7] Médecins Sans Frontières, "Frequently asked questions", http://www.accessmed-msf.org/campaign/faq.shtm No 19: Will lowering drug prices for poor countries hurt research and development (R&D) for new medicines?

[8] Médecins Sans Frontières, *Addressing the crisis in research and development for neglected diseases*. Jan 2006

[9] Stavudine (d4T) + lamivudine (3TC) + nevirapine (NVP)

[10] Médecins Sans Frontières, *Untangling the web of price reductions: a pricing guide for the purchase of ARVs for developing countries*. 8th edn, June 2005, page 10

[11] For instance efavirenz (EFV or EFZ), lamivudine (3TC), nevirapine (NVP), stavudine (d4T) or zidovudine (ZDV or AZT)

[12] For instance abacavir (ABC), didanosine (ddI), lopinavir/ritonavir (LPV/r), nelfinavir (NFV), ritonavir or saquinavir (SQV)

[13] Médecins Sans Frontières, "The second wave of the access crisis: unaffordable AIDS drug prices… again", Dec 2005

[14] For instance, lopinavir/ritonavir (LPV/r) , nelfinavir (NFV), ritonavir or saquinavir (SQV)

[15] Global AIDS Alliance, *Children left behind*. Washington DC; Global AIDS Alliance, 2006

[16] *Declaration on the TRIPS Agreement and Public Health, adopted on 14 November 2001 by the Fourth Session of the WTO Ministerial Conference held in Doha, Qatar.*
http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

Further resources

Campaign for Access to Essential Medicines, Médecins Sans Frontières
http://www.accessmed-msf.org/

Médecins Sans Frontières (also known as Doctors Without Borders) has been campaigning on access to essential medicines since 1999. The campaign's website explains the issues and background. There are very useful FAQs, and links to many publications.

TRIPS and public health, WTO
http://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm

The World Trade Organization's webpage on public health concerns and TRIPS, including links to the full text of the agreement.

Health care and intellectual property, CPTech
http://www.cptech.org/ip/health/

The Consumer Project on Technology's webpage acts as a directory to a wide range of resources on these issues, including many governmental and legal texts and a contact list of activists.

Ip-health
http://lists.essential.org/mailman/listinfo/ip-health

Listserve for discussions on intellectual property and health issues

In-Depth Study Session on Intellectual Property and Human Rights
http://www.3dthree.org/en/complement.php?IDcomplement=39

Report of a study session on the impact of intellectual property rules on the rights to education, health and food, and the use of human rights rules and mechanisms to support development-oriented intellectual property regimes.

"Intellectual property, competition and development", Martin Khor, Third World Network
http://www.twnside.org.sg/pos.htm

Third World Network has several papers, briefings and books on intellectual property and TRIPS available on their website.

Patents and Medicine, Health Global Access Project
http://www.healthgap.org/camp/trade.html

Health Global Access Project (Health GAP) is a US-based AIDS activist organisation, and their website has many fact sheets, press releases and other material from their campaign on the impact of patent monopolies on access to affordable HIV/AIDS medicines.

Treatment Action Campaign
http://www.tac.org.za/

A South African campaign for greater access to HIV treatment for all South Africans. TAC was very active in opposing pharmaceutical companies who, in 2001, sought to block the South African government from licensing production of generic drugs.