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AIDS Drugs



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Written by
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One in eight South Africans, one in seven Kenyans, and one in four Zimbabweans has HIV/AIDS. U.S. Surgeon General David Satcher has likened the HIV/AIDS epidemic in Africa to the plague that decimated Europe in the fourteenth century.

Existing treatments, which enable many people with HIV/AIDS in the U.S. and other industrialized countries to live relatively healthy lives, are unavailable to all but a few people in Africa. Life-saving HIV/AIDS drug cocktails cost about \$12,000 a year in many African countries—vastly out of reach of all but a small handful of the growing African population with HIV/AIDS.

Addressing the HIV/AIDS crisis in Africa and around the world will require a massively accelerated prevention effort. It will also require revitalizing the decimated public health systems of developing countries and making quality health care much more widely available. This, in turn, will require major new investments in public health and the abandonment of structural adjustment requirements to collect "user fees" from people seeking health care. But for millions of people infected with the HIV virus, there is also a crying need to make life-saving drugs more available—and quickly.

Two ways to promote access to essential medicines involve compulsory licensing and parallel imports. The more important of

these policy tools, compulsory licensing, enables any government to instruct a patent holder to license the right to use its patent to a company, government agency, or other party. Zimbabwe, for example, could issue a license to a local company for an HIV/AIDS drug manufactured by Bristol-Myers Squibb. The Zimbabwean firm would then manufacture the drug for sale in Zimbabwe under a generic name, and it would pay a reasonable royalty to Bristol-Myers Squibb on each sale.

Compulsory licensing lowers prices to consumers by creating competition in the market for the patented good. Its impact is similar to the introduction of generic competition at the end of a drug's patent term—prices come tumbling down.

Compulsory licensing can lower the price of medicines by 75% or more.

Parallel imports involve imports of a product from one country and resale, without authorization of the original seller, in another, thereby allowing the buyer to search for the lowest world price. A

Namibian company or government agency, for example, might purchase HIV/AIDS drugs in France—assuming they are sold for a lower price in France—and then resell them in Namibia. Since the price of medicines is sometimes lower in the United States and other industrialized countries, parallel imports can be a tool to enable developing countries to lower prices for consumers.

Both compulsory licensing and parallel imports are permitted under the international trade rules established by the General Agreement on Tariffs and Trade (GATT) and administered by the World Trade Organization (WTO). They are regularly used in industrialized countries, including the United States, Japan, and the European Union. One of the GATT agreements, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), contains the international rules the WTO enforces on intellectual property (patents, copyrights, and trademarks). Industry, especially the pharmaceutical sector, exercised heavy influence over the TRIPS agreement negotiations, and many public

interest advocates generally believe the TRIPS agreement inappropriately favors corporations.

In general, the TRIPS agreement requires countries to adopt U.S.-style patent systems, which apply both to products and processes and last for 20 years. This has compelled many developing countries-which had followed the lead of virtually every industrialized country in enacting weak patent rules while they were still industrializing (many European countries did not recognize patents until the 1970s)-to refashion their patent rules dramatically. But whatever the TRIPS agreement's biases, and despite the requirements it imposes on signatory countries, it permits compulsory licensing and parallel imports. Yet, despite the WTO-legality of these policy tools, multinational pharmaceutical companies object to the practices, which they perceive as curtailing corporate profits. The U.S. government has adopted a similar view, strongly opposing developing country efforts to undertake compulsory licensing, parallel imports, or other similar measures to make HIV/AIDS drugs and other essential medicines more available and affordable to their people.

Problems with Current U.S. Policy

Key Problems

Despite the legality of compulsory licensing and parallel imports, and despite the public health emergency enveloping much of the developing world, the U.S. has actively opposed developing country efforts to implement compulsory licensing, parallel imports, or other measures to make life-saving HIV/AIDS drugs more affordable and available in their countries. Although it frequently argues-incorrectly-that compulsory licensing and the other measures are WTO-illegal, the U.S. also takes the position that it has the right and authority to demand that countries do even more to protect intellectual property rights than is required by the TRIPS agreement.

To justify this position, Washington echoes pharmaceutical industry claims that compulsory licensing unfairly impinges on corporate intellectual property rights. The companies' unstated, overarching concern is that the United States and other industrialized nations might follow developing countries in pursuing compulsory licensing and parallel imports to lower consumer prices. These industry claims, however, ignore the fact that compulsory licensing is part of the intellectual property system-it is one of the many limitations on patent rights, and patent holders know this when they receive a patent. In the United States, for example, compulsory licenses are regularly issued on products ranging from pesticides to pollution control devices to computer processing chips. And under WTO compulsory licensing rules, companies receive reasonable royalties when a patented invention is used.

The U.S. also champions the pharmaceutical industry's argument that the high cost of research and development (R&D) requires that companies be given freedom to charge whatever they want. But it is unreasonable to give a blank check to anyone who controls life-saving technologies. And several facts cast doubt on industry claims about R&D and profits, especially in the case of the developing world.

First, governments often finance the key R&D costs of important drugs. In the case of HIV/AIDS, for example, the two leading candidates for compulsory licensing are AZT and ddI, both of which were developed at the National Institutes of Health (NIH) at U.S. taxpayer expense. Both drugs have already generated huge profits for drug companies. Second, the drug companies routinely exaggerate the costs of developing new drugs.

Third, since compulsory licensing will increase company sales (as it lowers prices), this policy tool may not harm industry earnings at all, or it may hurt earnings less than initially appears to be the case. If compulsory licensing expands access to AZT and ddI in Africa and the developing

world without undermining high prices in the U.S. and Europe, the companies could come out ahead, since they are currently selling so little in developing country markets.

Fourth, developing country markets are a paltry income source for the multinational drug companies-representing only about 10 % of international sales, 1.6 % in the case of Africa. Lower revenues from developing countries, should they occur, would not affect company R&D efforts or profitability to any significant extent. Application of the intellectual property system in developing countries won't make much of a dent in company profits one way or another, but it can make a huge difference in people's access to medicines.

Finally, there is a moral issue: should people with HIV/AIDS in poor countries be denied available treatments so that companies can earn higher profits? Neither compulsory licensing nor parallel imports involves companies selling their products at a loss. These are not just academic arguments. The U.S. has exerted extraordinary pressure on developing countries to prevent them from pursuing compulsory licensing and similar strategies to make drugs widely available. Most notably, Washington has undertaken a massive bullying effort to get South Africa to repeal provisions of its Medicines Act that would help the country make essential medicines more accessible and affordable. A report from the State Department says, "All relevant agencies of the U.S. government-the Department of State together with the Department of Commerce, its U.S. Patent and Trademark Office, the

Office of the United States Trade Representative, the National Security Council and the Office of the Vice President-have been engaged in an assiduous, concerted campaign to persuade the government of South Africa to withdraw or modify" the Medicines Act provisions that give the government the authority to pursue compulsory licensing and parallel import policies. The State Department report explains how "U.S. government agencies have been engaged in a full court press with South African officials from the departments of Trade and Industry, Foreign Affairs, and Health" to pressure them to change the law. Vice President Gore has raised the issue repeatedly with South Africa's former Deputy President (now President) Thabo Mbeki.

The United States has withheld certain trade benefits from South Africa and has threatened trade sanctions (by putting South Africa on the "Special 301 Watch List" of countries receiving heightened U.S. scrutiny regarding trading practices) as punishment for Pretoria's refusal to repeal those provisions of its Medicines Act that offend the multinational drug companies. Washington has also enlisted the French, Swiss, and German presidents to raise the issue with top South African officials. And South Africa is not alone. Washington has undertaken similar actions against other countries-chiefly, Argentina, Brazil, Thailand, and India-that have enacted or considered intellectual property rules that would make essential medicines more affordable to their citizens.

Title:

Author: Stanley Kurtz

Source: Avert (international AIDS charity)

Date:

Web site: <http://www.avert.org/generic.htm>

In May 1999, the World Health Assembly, the policymaking body of the World Health Organization (WHO), passed a resolution that declared public health concerns "paramount" in intellectual property issues related to pharmaceuticals. Although Washington had vociferously opposed

earlier efforts to obtain passage of a similar resolution that said public health concerns should take priority over commercial matters, the U.S., after insisting on minor changes, voted in support of the 1999 resolution. It is now time for Washington to bring its foreign policy into compliance with the accepted notion that public health protection is the most important goal in shaping pharmaceutical patent policy.

First, the U.S. should announce that it will terminate all bilateral pressure on South Africa, Thailand, Brazil, Argentina, India, and other countries for pursuing compulsory licensing policies, parallel imports, or any other WTO-legal policy. Instead, Washington should formally declare that it accepts the legitimacy of compulsory licensing and should immediately lift all sanctions currently in place against countries in retaliation for pursuing any intellectual property policies designed to make vital medicines more available to those in need.

Second, pending legislation should be altered. The African Growth and Opportunity Act currently conditions new benefits to developing countries on whether they enforce "appropriate policies relating to protection of intellectual property rights." Such provisions should either not be enacted into law or should be revised to clarify that "appropriate policies" include compulsory licensing and other measures that help to make life-saving drugs more widely available.

Third, rather than using the millennial round of WTO negotiations in Seattle this fall to tighten intellectual property requirements related to pharmaceuticals, the U.S. should lead the way in calling for a review of the existing TRIPS agreement and its effect on access to HIV/AIDS and other essential medicines. Among the pertinent questions: Have TRIPS rules undermined the ability of developing countries to maintain domestic pharmaceutical industries? If so, what impact has this had on consumers? Have TRIPS rules promoted new multinational corporate investment in research to treat and prevent diseases of particular concern to developing countries?

Fourth, the U.S. should immediately license to the WHO all of the HIV/AIDS drugs that have been developed with government funding and for which the U.S. government holds patent or other intellectual property rights. Existing law permits Washington to take such steps. With a license, the WHO could contract with private generic makers to produce the medicines and distribute them widely in the developing world. Since many of the most important HIV/AIDS remedies—such as ddI—were developed with significant U.S. government funding, the U.S. government controls rights to many important HIV/AIDS treatment pharmaceuticals.

Finally, it should be reiterated that although access to essential medicines is of critical importance, much more must also be done to prevent the spread of HIV/AIDS and to improve treatment of those infected. An essential step in combating the transmission of this disease is to cancel the foreign debts of the poorest countries, since debt servicing siphons off funds from investment in public health. World Bank and IMF structural adjustment programs that impose policies—such as requiring copayments from indigent patients—also make it more difficult for those with HIV/AIDS to gain access to medical care. And African governments must do more to support AIDS education and prevention efforts and to destigmatize people with the disease.

Robert Weissman is editor of Multinational Monitor magazine and co-director of Essential Action, a corporate accountability group. He is coauthor of Corporate Predators: The Hunt for MegaProfits and the Attack on Democracy (Monroe, ME: Common Courage Press, 1999; see <http://www.corporatepredators.org>).

Over the past decade activist pressure, the emergence of competition from generic manufacturers, and direct negotiation with pharmaceutical companies have all contributed to a dramatic drop in the price of certain drugs to treat HIV/AIDS in developing countries.

The availability of cheap antiretroviral drugs has been instrumental in treatment scale-up for resource-poor settings hard hit by the [AIDS](#) epidemic. Three million people in low- and middle-income countries are currently receiving drugs to treat HIV/AIDS¹. This would simply not have been possible without reduced price antiretrovirals.

Despite significant advances, a number of problems related to the price of anti-AIDS drugs remain. Not all drugs to treat AIDS are available at a suitably cheap price for poor countries, meaning that many of the newer, more effective drugs are only available in the West. This page looks at how the initial price reductions were achieved and the problems that many developing countries still face in accessing cheap, appropriate antiretrovirals.

Reducing the price of HIV/AIDS treatment

Access to antiretroviral (ARV) treatment in Botswana

In 1996, HAART - an effective combination therapy that delays the onset of AIDS - became available to those living with HIV in rich countries². Within four years, death rates for people with HIV/AIDS in developed countries had dropped by 84%³.

At a cost of US\$10,000-15,000 per person per year, these [antiretroviral drugs](#) (ARVs) were far too expensive for the majority of HIV infected people in resource poor countries. Five years after HAART therapy was introduced in the West, fewer than 8,000 people in sub-Saharan [Africa](#) were receiving the life-saving drugs⁴. In order for treatment to reach people living with HIV in the developing world, the price of the drugs clearly needed to come down to an affordable level.

At the beginning of the new millennium there was a breakthrough in treatment provision for resource poor areas when an Indian pharmaceutical company started to produce generic antiretrovirals that were exactly the same as brand versions made by

large pharmaceutical companies, but significantly cheaper. This sparked a price war between branded and generic drug makers, which forced the large pharmaceutical companies to lower the price of their AIDS drugs. This competition, coupled with pressure from activists, organizations - such as the Clinton Foundation - and governments of poor countries with severe AIDS epidemics, dramatically reduced the price of ARVs for developing countries. By the middle of 2001, triple combination therapy was available from Indian generic manufacturers for as little as \$295⁵.

The price of antiretrovirals for low- and middle-income countries has continued to fall. Between 2004 and 2007, the prices of most first-line drugs decreased by 30-64%⁶, making the most common antiretroviral combination (3TC/d4T/NVP) available for only US\$87 per patient per year⁷.

The role that generic drug production and price negotiations with multinational pharmaceutical companies played in lowering the price of antiretrovirals will now be looked at in more detail.

Generic drugs

A generic drug is an identical copy (bioequivalent) of a brand name (or proprietary) drug. Generics are exactly the same as their branded counterparts in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use. The notable difference between the two is the price.

Generic drug manufacturers incur fewer costs in creating the generic drug, as they do not have to cover the expense of drug discovery, or lengthy safety and efficacy trials. Instead generic makers reverse-engineer known drug compounds. This means that generic manufacturers are able to maintain profitability while offering the drug at a much lower cost.

This is problematic for pharmaceutical companies who argue that generic copying reduces their profits and decreases the amount of money they can spend on

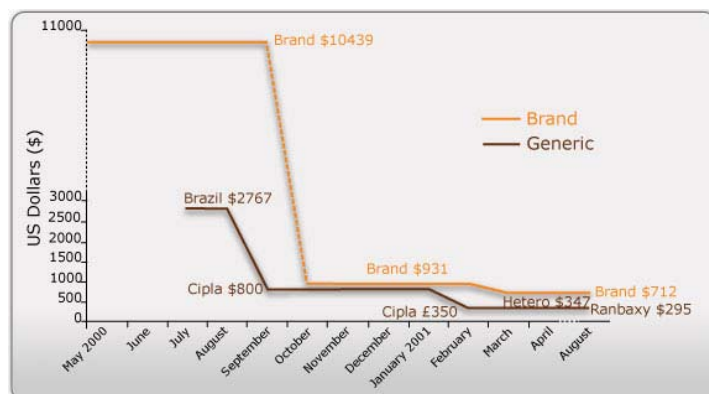
researching and developing new drugs. In order for the proprietary drug makers to recoup the money they spent on drug creation, they are granted a 'patent' (an intellectual property right), which is an exclusive right that prevents others from making, using, selling, offering to sell, or importing their drug. The patent typically lasts for twenty years.

Legislation in favour of the pharmaceutical industries' right to patent their drugs - TRIPS - was introduced in 1995. TRIPS - The Agreement on Trade Related Aspects of Intellectual Property Rights - introduced intellectual property law into the international trading system for the first time and applies to all members of the World Trade Organisation (WTO). Because the implementation of TRIPS was to have a huge impact on generic drug production, the majority of developing countries were given a ten-year transition period in which to comply. This means that developing countries (such as India) were able to continue developing generic drugs until 2005, whilst least developed countries have until 2016.

Generic drugs, FDC's and AIDS

In 2001, Indian generic drug manufacturer, Cipla, announced that it would sell a generic copy of a triple-therapy antiretroviral for US\$350 per patient per year. This had an incredible impact as the competition this generated dramatically drove down the price of anti-AIDS drugs for developing countries, thereby increasing the range of affordable options for national treatment programmes.

The graph below illustrates the effect of generic competition on propriety drug prices between 2000 and 2001. It shows the lowest world price per patient per year of triple combination therapy made up of d4T (stavudine) + 3TC (lamivudine) + nevirapine⁸.



[India](#) is the largest supplier of generic ARVs to low- and middle- income countries, exporting two thirds of the drugs it manufactures⁹. [Brazil](#), [Thailand](#) and [South Africa](#) also produce a significant amount of generic drugs and have used their expertise to help a number of African nations - such as [Zambia](#), Ghana, Tanzania, [Uganda](#), Ethiopia and [Zimbabwe](#) - develop local AIDS drug manufacturing facilities¹⁰.

In 2008 UNAIDS reported that national governments of 94% of countries with generalised epidemics, and 61% of countries with concentrated epidemics, had national policies for using generics to promote antiretroviral access¹¹.

The manufacture and export of generic drugs was not only a turning point in terms of the price of ARVs, but also helped to revolutionise treatment for resource-poor settings by simplifying HIV/AIDS treatment. In 2001, an Indian generic manufacturer produced a combination of three antiretrovirals (patented by different pharmaceutical companies) into a single pill, known as a fixed dose combination (FDC). This was only possible because India did not have to abide by TRIPS legislation at this time and was therefore able to ignore the patents on the drugs.

FDCs were a significant innovation as they reduce the number of pills taken each day. Because FDCs are easier to manage - for both patients and health workers - they increase adherence, thereby reducing the incidence of [drug resistance](#). The drugs were also available in heat resistant forms, which proved extremely valuable for use in the

developing world, where often there is scarce access to refrigeration facilities.

Generic antiretrovirals are now widely used to treat HIV/AIDS in the developing world. They have been integrated into many treatment programmes including [PEPFAR](#) - the President's Emergency Plan for AIDS Relief. PEPFAR, the single greatest supporter of treatment provision for AIDS in the developing world, began to distribute generic drugs through its programmes in 2004-5. In 2007, generics accounted for 57% of the \$131 million PEPFAR spent on anti-AIDS drugs¹².

The role that the production of generic drugs had on the distribution of treatment for developing countries cannot be underestimated. Quite simply, as Stephen Lewis, former UN Special Envoy for AIDS in Africa, said: '...we wouldn't have this extraordinary run of treatment in Africa now if it weren't for the generic drugs.'¹³

Pressure and negotiation with 'Big Pharma'

In the early 2000s large pharmaceutical companies (known as 'Big Pharma') manufacturing drugs to treat HIV/AIDS were subject to intense pressure to lower their prices. Organizations such as the Clinton foundation, Medecins Sans Frontier and (more recently) UNITAID, alongside AIDS activists and a number of national governments, all worked to achieve price reductions.

In May 2000, five pharmaceutical companies offered to negotiate steep cuts in the price of AIDS drugs for regions severely affected by the AIDS epidemic. Dr. Rolf Krebs, vice chairman of Boehringer Ingelheim recognised that this was "... the first time that both the public and private sector are joining forces to implement a major change in the care of HIV/AIDS in the developing world." Although significant price reductions were achieved, the drugs remained prohibitively expensive for many poor countries. Dr. Peter Piot, the executive director of UNAIDS, called the negotiations "...a promising step in a long-term process", whilst Medecins Sans Frontier called the

negotiations "...a victory, but a small one, much like an elephant giving birth to a mouse"¹⁴.

Around the same time, the Clinton administration issued an executive order which promised that the US government would not interfere with African countries that violate American patent law to obtain cheaper AIDS drugs.

South African AIDS activists

In 2001 -following the end of his second term as President of the United States - Bill Clinton confirmed his commitment to HIV/AIDS drug provision when he established the William J. Clinton Foundation, containing an HIV/AIDS programme. Using the former President's contacts and knowledge, the foundation has continually worked to increase access to treatment by negotiating pricing deals with drug manufacturers and working to improve health care services in developing countries¹⁵. Medecins Sans Frontier does similar advocacy work and runs a major Campaign for Access to Essential Medicines¹⁶.

Another significant event in drug price reduction also came in 2001 following an attempt by thirty-nine major pharmaceutical companies to prosecute [the South African government](#) for passing a law that allowed easy production and importation of generics. Big Pharma was eventually forced to back down and drop the case following a tremendous outcry from the international community including the South African government, the European Parliament and 300,000 people from over 130 countries that signed a petition against the action, angered over the apparent pursuit of profit over public health. One of the pharmaceutical companies involved in the case, GlaxoSmithKline, even granted permission (called a voluntary licence) to major South African generics producer Aspen, to share the rights to their drugs AZT, 3TC and the combination Combivir without charge¹⁷. This was a significant case as it brought access to medicines for poor countries into the public consciousness.

More recently, in 2006, UNITAID - an international drug purchase facility - was established to ensure a stable source of funding for drugs to fight HIV/AIDS, malaria and tuberculosis. UNITAID has partnered with the Clinton Foundation since 2006, negotiating with manufacturers, including generic producers, to continually lower the price of AIDS drugs and supply them in over 70 developing countries. They state that they have managed to reduce the price of leading [child HIV treatment](#) regimens by 64 percent and the price of leading adult regimens by 43 percent in lower-income countries. In 2009, they announced they had reduced the price of a convenient once-daily pill (combining generic drugs tenofovir, lamivudine and efavirenz) by 30 percent compared to the price they had negotiated in 2008. They have also encouraged more suppliers to enter into the paediatric and second-line therapy markets which have not been seen by manufacturers as lucrative markets due to constraints on patent, lower demand, and more complex production techniques.¹⁸

What has emerged from the negotiations with Big Pharma is a system of 'tiered' pricing. Tiered pricing means that the price at which the big pharmaceutical companies sell their drugs is calculated using formulas based on average income per head, leading to lower prices in poor countries¹⁹.

"Preferential pricing is the only way how we can meet both conflicting needs in the fight against AIDS. We can refinance our high research and development costs for innovative, new treatments by the established price system in industrialised countries and can offer affordable medicines to patients in poor countries who otherwise cannot afford antiretroviral medication" - *Alessandro Bianchi, chairman of Boehringer*²⁰

Although this system is beneficial to the large pharmaceutical companies, there are concerns that the system is overcomplicated and overdependent on the goodwill of Big Pharma.

AIDS, TRIPS and second-line therapy

Demonstrators protesting GlaxoSmithKline's policies regarding generic AIDS drugs in Africa

Since 2005, developing countries that are members of the WTO (such as India, Thailand and Brazil) have been required by TRIPS to issue patents. Obliging developing countries to comply with patent legislation has complicated the provision of HIV treatment. This is because although patents have expired on a number of first-line AIDS drugs (making them available cheaply from generic makers), patents still exist on most new and second-line medicines.

This is problematic as modern antiretroviral drugs are generally less toxic, easier to take and more effective at fighting HIV. They are often needed when a patient has to change their antiretroviral regime due to toxicity or resistance. Drugs used to combat resistance are called second-line drugs. They are very important to HIV treatment programmes as 10-15% of people taking antiretrovirals will develop resistance to the combination of drugs that they are taking within 4-5 years²¹.

TRIPS has stifled the generic competition that drove the price of first generation antiretrovirals down, causing huge disparities in the price of first- and second-line ARVs. In 2007 the median cost of the most commonly used second-line regime was US\$1214 in low-income and US\$3306 in middle-income countries.²² The huge difference in price between first- and second-line treatment has created imbalances in national health expenditures, which will be difficult to sustain. In [Brazil](#), for example, the Ministry of Health currently spends 80% of its budget on imported patented drugs, even though they represent only a small proportion of drugs used²³.

The consequence of TRIPS is that the new, better drugs are only available in countries that have the capacity to cover the high cost. Poor countries are forced to wait until their patent expires or the proprietary prices are forced down. The access gap between people in wealthy and developing countries has angered many, who feel that TRIPS further exacerbates difficulties in supplying antiretroviral drugs to poor countries and puts the profit margins of Big Pharma before public health. It is felt that if the capacity to provide generic effective, yet cheap anti-AIDS treatment to the developing world exists, then it is immoral not to allow the production of drugs that will save millions of lives.

"We're starting from zero again... by the time generic competition kicks in for the newer drugs, millions of people will have died unnecessarily."

MSF campaign for access to essential medicines²⁴

In light of these concerns, the WTO proposed two means by which generic versions of drugs under patents may be produced.

The first is called 'voluntary licensing'. A government, an individual, or an organization can request a voluntary license from a patent holder (usually a large pharmaceutical company) to allow generic drugs to be supplied during a public health emergency, either through imports or by local production. A number of voluntary licenses have been granted to date including a licence granted by Merck for South African generic producer Aspen Pharmacare to produce efavirenz²⁵. The drawback of voluntary licenses is that they depend on the goodwill of the patent holder, and can be lengthy to negotiate.

The second option, 'compulsory licensing', is discussed below.

Compulsory licensing

Legally a country can get around TRIPS patent enforcement by issuing a compulsory licence. A compulsory licence is a government licence that enables someone other than the patent holder to copy patented products and processes without fear of prosecution. Governments can issue them if a patent owner abuses their rights by, for example, failing to offer their product on the market, or offering it at a price that is too high for potential buyers to afford. Normally, to copy drugs for this reason, the generic company has to negotiate with the original manufacturer to agree royalties (money paid to the patent holder to make up for the loss of profit exclusivity). However, following the 2001 Doha agreement a country can issue a compulsory licence for a drug that treats a disease causing a severe health emergency in that country without royalties being paid.

Although in theory compulsory licensing offers a legal solution to patent protection for HIV/AIDS treatment, in practice it is difficult to exploit for the following reasons:

- Generic manufacturers are limited to producing only the quantities predefined in each compulsory licence. This curbs the large-scale production that is required to deliver drugs cheaply.
- Certain large pharmaceutical companies have demonstrated that countries that issue compulsory licences may face repercussions (see below).
- It was ruled that licences should be granted 'predominantly' to supply the 'domestic market', making it difficult for poor countries lacking technological capabilities to access generic drugs.

This final point was a particular point of contention for those concerned with providing ARVs to the developing world as it was felt that this effectively penalised the

world's poorest countries that were already struggling to roll out HIV treatment.

The World Trade Organisation (WTO) therefore issued the so-called 'paragraph 6 waiver' which allows members who are unable to produce pharmaceuticals at home and are suffering a serious health crisis to import generics from other nations under compulsory licences (providing exported drugs are not part of a commercial or industrial policy of the exporting country)²⁶. Despite endorsement by the WTO, because of its complicated nature, compulsory licensing has been used very little by low- and middle-income countries. In fact, to date Thailand is the only country to have issued a compulsory licence for an antiretroviral drug and provides an excellent example of why other countries have been reluctant to follow suit.

[Thailand](#) has issued a number of compulsory licences for antiretroviral drugs including Merck & Co.'s Sustiva® (efavirenz) in 2006 and Abbott's Kaletra® (a combination of lopinavir & ritonavir) in 2007^{27 28}. Abbott – which is the tenth largest pharmaceutical company in the world - was angered that Thailand had 'ignor[ed] the patent system' and retaliated by announcing that it would not be applying for licences to sell seven of its newest products in Thailand (one of which was a new once-a-day heat resistant form of Kaletra® which would have been extremely useful in the hot Thai climate)²⁹. Thailand was also placed on a US Trade Representative 'priority watch list' of countries seen to be committing intellectual property piracy³⁰.

Although this was detrimental for Thailand, it has helped to reduce the price of Kaletra by half in many developing countries³¹.

In 2007, Brazil issued a compulsory license to produce a lower-cost, generic version of Merck's antiretroviral Efavirenz. Recognising the repercussions that Brazil may face, President Luiz Inacio Lula da Silva said:

Between our trade and our health, we have chosen to look after our health."³²

The way forward

For the moment, most people that need antiretrovirals in the developing world have a non drug resistant form of the virus, and can therefore take first-line therapy. However, as treatment becomes more widespread, and resistance increases, the high price of second-line drugs is going to become a major issue. Addressing this issue will become increasingly important to ensure the most cost-effective use of available resources and the sustainability of treatment programmes³³.

Some countries, such as Thailand and Brazil, have found innovative ways of securing cheaper second-line drugs. But the problem is that these options are limited to countries with political clout and financial stability and autonomy. As is all too often the case, it is the poorest countries already struggling to manage their HIV epidemics that are the least likely to benefit from the current system.

Some have suggested that the only way forward is to abolish the TRIPS system for medicines altogether, and replace it with an alternative form of remuneration and reward for innovative research and development. This is extremely unlikely, and an alternative solution needs to be found.

One idea, being spearheaded by UNITAID, is the creation of a "patent pool." The pool would hold licences on various patented medicines, which generic companies could then produce at a lower cost for poor countries³⁴. Although the creation of a patent pool for HIV/AIDS drugs is at an early stage, there is hope that it will make the production of generic versions of antiretrovirals easier to negotiate and therefore faster and more efficient.

Unfortunately, any such radical changes to the current system are unlikely any time soon, leaving it up to governments, drugs manufacturers, campaigners and non-governmental organisations to force the price of AIDS drugs down, enabling health authorities to secure the drugs their people so desperately need.

Title: Aids drugs and the developing world
 Author: BBC
 Source: LifeSiteNews
 Date: Friday, 26 November, 1999
 Web site:
http://news.bbc.co.uk/2/hi/health/medical_notes/a-b/537714.stm

Aids drugs & the developing world

Developing countries cannot afford Aids drugs

Treatments for Aids can be made available to the developing world through cheap, local production, but this is often barred by the West.

Why do developing countries want to produce drugs locally?

By manufacturing generic drugs within the developed world, it is possible to provide them to local people at much more affordable rates than if they are forced to pay the global price set by Western producers who hold the patent.

If the drugs are not provided cheaply from local production they are out of the price range of local people. Medical organisation Medecins Sans Frontieres (MSF) says doctors in Kenya advise Aids patients "to save up for their funeral" rather than drugs, as they are not affordable to them.

What is stopping them doing so?

The United States in particular has been accused of stopping the developing world from producing drugs generically, insisting they import American-made drugs at Western prices. Thailand, for instance, has faced trade sanctions on its own exports.

However, the Trade-Related Aspects of Intellectual Property Rights agreement (TRIPS) allows for so-called "compulsory licensing" in cases of public health emergencies or unfair pricing. This allows

countries to produce drugs which are under patent.

How much cheaper are generic drugs?

Generally, they are around 70 to 90% per cent cheaper, according to MSF. In some cases they can be 200 to 300% cheaper than the branded equivalents made in the West.

Flucanazole, a drug which manages cryptococcal meningitis, an infection affecting one in five of Aids sufferers in Thailand, was supplied exclusively by US company Pfizer until 1998. Since local alternatives became available, the cost of a daily dosage of 400mg has fallen from US\$14 to 5% of that price. This represents a saving per year of US\$3m to the Thai government each year.

The US\$0.75 a day price in Thailand compares to a US\$20 a day cost for patients in Kenya.

Thailand's Government Pharmaceutical Organisation has supplied generic zidovudine - an antiretroviral drug - since 1993. The resulting competition has led to a fall in price of US\$324 in 1992 to US\$87 in 1995.

Are they as effective?

Yes. MSF says there is no evidence that generic drugs produced in the developing world are any less effective than branded versions manufactured in the West.

Nathan Ford, of the organisation's Campaign for Access to Essential Medicines, says: "MSF as a medical organisation is the first to ensure absolute quality guaranteed on these drugs."

The National Aids Trust points out that local regulation has an effect on the quality of drugs but adds that there is no reason in principle why locally-produced versions should be any less effective.

Title: New 20 year patents threaten to end AIDS drugs for developing countries

Author: Owen Dyer

Source: BJM

Date: September 25, 2006

Web

site:

<http://www.bmj.com/cgi/content/full/329/7478/1308-c>

Efforts to bring antiretroviral treatment to AIDS patients in developing countries are threatened by the looming implementation of new World Trade Organisation's patent rules, the charity Médecins Sans Frontières warned this week.

The organisation's TRIPS (trade related aspects of intellectual property rights) agreement comes into force for most signatories on 1 January 2005. It requires the organisation's members to grant 20 year patents to new pharmaceutical products. Only the least developed countries can postpone implementation until 2016.

Médecins Sans Frontières' international president, Dr Rowan Gillies, told the *BMJ*: "We're gravely concerned that our sources of affordable medicines will dry up. Not only are patents going to be granted on all new medicines, some existing medicines that we rely on will be reviewed for possible patent protection as well."

Dr Gillies said he is particularly worried about the effect on the generics industry in India, which produces most of the generic, fixed dose combination antiretrovirals currently used by his charity.

The charity is currently treating 23 000 HIV positive patients in 27 countries in Asia, Africa, Latin America, and eastern Europe—more than double the number it treated last year.

Dr Gillies said: "We're not ideologically attached to generics, but we've found it's what works best. At the moment, only generics can provide a treatment regimen of just two pills a day. That's essential for compliance and good results."

Dr Arnaud Leannin, who works with Médecins Sans Frontières' AIDS programme in Malawi, said: "Although they are not the final answer to AIDS, triple drug cocktails literally allow people to rise from their death beds and live normal, longer lives." Two year survival rates in the programme attained 85%, he added.

But Pietro di Mattei, medical coordinator of the charity's Mozambique AIDS programme, said that growing numbers of patients are now failing first line treatment and the charity has to buy patented medicines for second line therapy. The cost of annual treatment in these cases jumps from \$250 (£131; €188) a year to \$700-\$3000. Patients needed cheap, second line formulations adapted to resource poor settings, he said.

Other priorities identified by the charity's fieldworkers were a simple blood test for CD4 count and viral load, more sensitive tests for tuberculosis, combination antiretrovirals that are not incompatible with tuberculosis drugs, and a fixed dose formulation for children.

Médecins Sans Frontières spelt out its concerns at a press conference in London on 30 November, the day before World AIDS day. "There are about five and a half million people in developing countries who need antiretroviral treatment now if they are to expect to survive two years," said Dr Gillies. "Only about 440 000 are getting it."

Title: Canada to allow production of generic AIDS drugs

Author: Stanley Kurtz

Source: LifeSiteNews
 Date: November 2003
 Web site:
<http://www.nature.com/nrd/journal/v2/n11/full/nrd1237.html>

Canada to allow production of generic AIDS drugs

In a surprising move, Paul Martin, the Canadian Prime Minister-elect, has endorsed plans for the federal government to excuse poor countries from patent rules, as permitted under a new international agreement. This allows Canadian generic drug-makers to supply cheap medicines to developing countries undergoing health crises. The World Trade Organization (WTO) deal creates a legal loophole that allows the most desperate countries to override patents on expensive drugs and order cheaper copies from generic manufacturers, with patent holders receiving a small payment. In fact in 2000, Canadian generic pharmaceutical manufacturer Apotex offered to provide HIV/AIDS drugs to developing countries in sub-Saharan Africa at cost. Ultimately, this did not happen because Canadian patent law would not allow it. Canadian law protects patented medicines for 20 years, except for national distribution in emergencies. Eric Dagenais, director of patent policies for the Industry Ministry, said he would like to propose a bill in the next few weeks or months to the cabinet, which would allow Ottawa to force drug-makers in Canada to surrender their patents on AIDS drugs. Canada is the first G7/G8 nation to take such a step. Canada's research-based pharmaceutical companies will work with Ottawa to implement a WTO agreement to import cheaper drugs to developing nations, providing the countries can prove that they do not have the capacity to make the drugs themselves and that they are not going to sell the drugs on the black market.

This announcement follows on from progress made at the November 2001

international trade meetings in Doha, Qatar, when it was agreed that developing countries could import low-cost generic medicines in times of health crises. Many of the countries stricken with diseases such as HIV/AIDS do not have the domestic manufacturing capabilities to produce their own low-cost versions of the necessary drugs.

Title: W.H.O moves to make AIDS drugs more accessible to poor worldwide
 Author: Donald McNeil Jr
 Source: New York Times
 Date: 23 April 2002
 Web site:
<http://www.virusmyth.com/aids/news/nytwwho.htm>

W.H.O. MOVES TO MAKE AIDS DRUGS MORE ACCESSIBLE TO POOR WORLDWIDE

By Donald McNeil Jr.

New York Times 23 April 2002

Paris -- Helping clear the way for Western-style AIDS treatment to reach even rural Africa, the World Health Organization released new guidelines today describing the drug cocktails that work best and the simplest acceptable laboratory tests for patients.

The guidelines are meant to show doctors in poor areas how to prescribe powerful "triple-therapy cocktails" safely.

In addition, the W.H.O. today added 12 antiretroviral drugs to its

essential drugs list to encourage price competition between patent-based and generic companies and prod the latter to make more three-drugs-in-one-pill dosages.

The two moves are "vital steps in the battle against the AIDS pandemic and should encourage both industrialized and developing country governments to make H.I.V. treatment more widely available," said Dr. Gro Harlem Brundtland, the director-general of the health organization.

Carmen Perez, pharmaceutical director for the Doctors Without Borders campaign to make drugs cheaper, called today's W.H.O. decision a "very good victory."

The moves "show that treatment can be done," she said. "It will be difficult, but what can we do about that? There are 40 million infected people out there. There are no excuses. We're already late."

The health organization's announcement is also meant to silence several sets of critics: drug industry executives who have argued that triple therapy is too complex and dangerous for poor, illiterate patients; AIDS skeptics like President Thabo Mbeki of South Africa who argue that the drugs don't work or are

toxic; and experts who confuse public health doctors in poor countries by overwhelming them with competing drug combinations.

Of the 40 million H.I.V.-positive people in the world, about 6 million are sick enough to need antiretrovirals now, the health organization estimates. Less than 5 percent get them because of the drugs' cost and the costly tests used in the West to monitor them. Some tests like CD-4 cell and viral load counts cost up to \$1,000 and require equipment unheard of in rural clinics. The health organization hopes that, by 2005, if African and Asian health systems can stand the strain, up to three million people will be getting treatment.

It recently convened 100 AIDS doctors from 30 countries to come up with four tiers of minimally acceptable tests, said Dr. Basil Vareldzis, who helped write the new guidelines.

The "absolute minimum" tier was an H.I.V. test and a hematocrit, which measures the percentage of red cells in blood. "If your lab can't do those, you shouldn't be giving out antiretrovirals," Dr. Vareldzis said. Since AZT, a common antiretroviral, can cause anemia, "you could run the risk of killing somebody."

The next "basic" level includes blood tests that require equipment widely available in most district hospitals, even those in Africa. The equipment tests white blood cell counts and does simple liver tests.

The white cell count is a proxy for a CD4 test, which measures "helper T-cells" that set off immune responses. In the West, a CD4 count below 200 per cubic millimeter usually prods a doctor to prescribe antiretrovirals. But white cell counts move roughly up and down with CD4 levels, so white blood cell counts below 1,200, plus clinical signs of AIDS are enough, under the new guidelines, to justify starting the therapy.

"If someone has night sweats and weight loss and is definitely H.I.V. positive, you can't ethically deny them drugs just because you can't do a CD4 test," Dr. Vareldzis said.

Antiretrovirals can poison the liver, but simple liver tests plus eyes yellowed by jaundice or tender abdomens could be proxies for expensive toxicity tests in deciding whether to change drugs.

The health organization is also listing which drug cocktails it thinks should be tried first. Essentially, it suggests a mix of AZT, which is also called zidovudine, plus 3TC,

which is also called lamivudine, plus a third drug like nevirapine or efavirenz or abacavir, depending on factors that include whether a patient is pregnant or hypersensitive to abacavir.

Making this an official recommendation "is a way to avoid all the waste and confusion and tendency to create resistance that exists in all the weird combinations that people came up with before," said Dr. Jonathan Quick, the health organization's director of essential medicines.

Listing the best drugs encourages makers of generic drugs to put three drugs in one pill, making it much easier for patients to take their medicine correctly, he added.

Three-in-one pills aren't made by the pharmaceutical giants because they would have to share their drug patents, which might violate antitrust laws.

The additions to the essential drugs list are abacavir, didanosine, efavirenz, indinavir, lamivudine, lopinavir, nelfinavir, ritonavir low-dose, saquinavir and stavudine. Zidovudine and nevirapine were already on it for mother-child transmission, but can now be given to adults.

The introduction of triple-therapy in the United States in 1996 led to a 70 percent decline in AIDS deaths.

Dr. Harvey E. Bale Jr., director of the International Federation of Pharmaceutical Manufacturers Associations, which represents the major pharmaceutical companies in talks with the health organization, did not oppose putting patented drugs on the essential drugs list.

The industry, he said, has recognized the need to get AIDS drugs to the world's poor quickly and has lowered its prices until its AIDS drugs are competing with their generic counterparts. He cautioned that safe three-in-one pills were difficult to develop and must be thoroughly tested, and he complained that the health organization had rushed the guidelines through without its normal period for public comment.

On March 20, the organization released its first list of manufacturers of AIDS drugs whose factories it had inspected and ruled safe.

In a surprise to advocates for the poor who have called the organization overcautious and beholden to big drug companies and the United States, the list included generic makers from India and elsewhere.

"Countries now have the three bits of information they need - the names of the drugs, the quality assurance and the treatment guidelines," Ms. Perez said.

Title: Brazil fights for accessible anti-AIDS drug

Author: Berta Joubert-Ceci

Source: Workers World

Date: July 2, 2005

Web

site:

<http://www.workers.org/2005/world/brazil-0707/>

Since early June, the government of Brazil has been focusing on the task of securing the supply of antiviral medication to its HIV-infected population. On June 1, a commission from the Brazilian House of Representatives approved a bill that prohibits the patenting of vital drugs for the prevention and treatment of the disease. This makes it possible for state pharmaceutical laboratories to manufacture as generic otherwise expensive anti-HIV drugs.

Roberto Gouveia from the ruling Workers Party (PT), author of the bill, said that "it aims to promote well-being and to advance a humanizing model; we cannot remain subject to profits."

Brazil is encouraging other countries to take advantage of World Trade Organization rules and not be beholden to voracious pharmaceutical companies that, with their extraordinarily high prices, put people's health and well-being at risk. The WTO agreements on intellectual property allow governments to produce a generic version of a high-priced patented medicine if an agreement cannot be reached with the patent company and there is a health threat.

Most recently, Brazil alarmed greedy U.S. pharmaceutical Abbott Laboratories when it announced June 24 that it would break the patent for Abbott's drug combination of Lopinavir and Ritonavir, named Kaletra,

unless Abbott lowers its high price or allows Brazil to manufacture a generic version.

The Associated Press reported June 24, "Health Minister Humberto Costa said Brazil is able to act on its own because it has legislation that allows the government to break drug patents in cases of a health emergency or if it rules the pharmaceutical industry is engaged in abusive pricing."

Abbot and some reactionary voices in the United States have responded that Brazil does not have an AIDS emergency. That's a typical answer from a callous for-profit medicine manufacturing company. But it is Brazil's aggressive prevention programs that have kept AIDS from being an epidemic for millions of Brazilians.

Brazil is recognized internationally as a leader in AIDS prevention and treatment programs that are available absolutely free to anyone who needs them. Brazil has been criticized by the religious right wing, particularly in the United States, for its non-sense, non-discriminatory policy.

In May, Brazil publicly criticized the Bush administration's anti-abortion and pro-abstinence AIDS program and rejected \$40 million in aid for anti-HIV programs. Brazil refused to sign on to a declaration condemning prostitution. Officials said that would have interfered with helping sex workers to protect themselves and their clients from infection.

Organizations provide free condoms and carry out an extensive prevention program, including treatment and care of orphan children.

The Brazilian anti-HIV program has been an example that many other developing nations are following. It has been praised by many organizations worldwide, including the World Health Organization and the Gates Foundation.

In 2003, the WHO announced that it would use the Brazilian program as a model to treat poor people infected with the virus. That same year, Bill Gates' foundation awarded \$1 million, stating: "Brazil has shown that with perseverance, creativity and compassion, a country whose people are affected with the AIDS virus can fight

against the epidemic. Brazil is saving lives and saving resources at the same time; this should be an inspiration for the world."

But the high cost of newer essential drugs is jeopardizing the program. Health authorities say Brazil is now treating 170,000 patients with HIV/AIDS or other sexually transmitted diseases. However, an increase to 215,000 patients is expected by 2008.

A great many will be people over 50 years old, mostly women, who are now the fastest-growing sector of the population contracting the virus. In the last 10 years the number of cases of women over 50 grew 567 percent.

Abbott Co. officials have 10 days to respond to Brazil. If they do not lower the price or permit the production of a generic equivalent, Costa said that Brazil is ready to take action, and "will be issuing the compulsory license order." He added, "Brazil will follow through and break the patent."

The country is in similar negotiations with two other anti-HIV-drug manufacturers, Merck & Co. Inc. and Gilead Sciences Inc.

Title: Not enough being done to make essential AIDS drugs available

Author:

Source: Medicines sans frontières/Doctors without Borders

Date: March 28, 2006

Web

site:

<http://doctorswithoutborders.org/press/release.cfm?id=1765>

Not Enough Being Done to Make Essential AIDS Drugs Available

March 28, 2006

Geneva, March 28, 2006 — As the World Health Organization (WHO) and UNAIDS release a long-awaited report on their 3x5 AIDS treatment initiative, and call for universal access to AIDS drugs, the medical humanitarian organization Doctors Without Borders/Médecins Sans Frontières (MSF) is expressing concern that not enough is being done to make sure that the drugs needed to

expand and sustain treatment are accessible to those who need them.

WHO and donors alike are ignoring the looming threat to access to affordable essential medicines that form one of the key barriers to global treatment scale-up, MSF said. Growing numbers of people that have been on AIDS treatment for several years will increasingly need access to newer, second-generation medicines that remain priced out of reach or are not available at all. "We won't be able to keep our patients alive beyond the first few years unless there are some dramatic price reductions for second-line drugs," said Dr. Karim Laouabdia, director of MSF's Campaign for Access to Essential Medicines. "Patients will inevitably need second-line drugs after a few years on treatment, because resistance develops, even when every single pill is taken according to the treatment plan."

At the same time, World Trade Organization (WTO) rules on patents are threatening to dry up sources of low-cost generic versions, including some of the first-generation drugs. Without a reliable supply of low cost AIDS drugs, national governments and treatment providers will be faced with an uphill battle, and patients risk having vital treatment interrupted or priced out of their reach.

"It was generic competition and the absence of patents on first generation AIDS drugs in key producing countries that forced prices to drop drastically over the early part of the decade, helping expand treatment," said Ellen 't Hoen, director for policy and advocacy at MSF's Campaign for Access to Essential Medicines. "But we are loosing ground again. What we're witnessing now are patent regimes that threaten to block access to both first- and second-line drugs. It's a cruel case of *déjà -vu*, to which the WHO seems to be blind," she added.

Indian manufacturers are the source of 84 percent of antiretrovirals MSF uses in its AIDS treatment projects across the globe. Last year, India changed its patent law to comply with the WTO TRIPS Agreement, and three weeks ago, India granted its first ever patent on a drug. MSF is deeply concerned that this will set a precedent,

threatening access to other essential medicines including antiretrovirals, patents to some of which are being considered by the Indian patent office right now.

Pharmaceutical companies are faster in filing patents in developing countries than in delivering the drugs. As an example, Abbott Laboratories only sells in the US a new version of a WHO recommended second-line AIDS drug (lopinavir/ritonavir) that is particularly well-suited for use in developing countries because it does not need require refrigeration. MSF placed an order for the drug with the company's headquarters in Chicago, but so far, Abbott has refused to proceed with filling the order, and there are no alternative sources for this product today.

MSF warns that if there is no concerted effort by the UN and the international community to make sure there is a steady supply of low-cost AIDS drugs, attaining the goal of universal access will remain impossible.

Title: Cheap AIDS drugs for poor countries

Author:

Source: CNN Buisness

Date: June 7 2001

Web

site:

<http://edition.cnn.com/BUSINESS/programs/yourbusiness/stories2001/aids.drug.price/>

Cheap AIDS drugs for poor countries

LONDON, England (CNN) - One of the world's leading pharmaceutical firms has said it plans to cut the cost of its HIV/AIDS drugs in 63 of the world's poorest countries. GlaxoSmithKline (GSK) said it planned to offer the drugs at cost price to governments, aid agencies and churches in the Least Developed Countries (LDCs) and in all of sub-Saharan Africa.

The industry has been under increasing pressure from charity groups such as Oxfam and Medicins sans Frontieres to make drugs more widely available in countries where people cannot afford Western prices.

GSK said it would also make anti-malarial drugs available at cost price and it was setting up a corporate social responsibility committee chaired by its non-executive chairman, Richard Sykes.

The committee, made up of non-executive directors of GSK, will advise on social issues and keep the company's policy on health care in the developing world under review.

In an era when ethical issues are rising up the corporate agenda, institutional investors, as well as pressure groups, have urged GSK to take a more pro-active stance on the issue. GSK's chief executive Jean Pierre Garnier said the measures recognised the "ethical imperative" on the pharmaceutical industry to do more to tackle the problems faced by developing countries.

Keeping up the pressure

Oxfam, which has spearheaded a campaign to see the price of life-saving medicines cut in poor countries, welcomed GSK's decision, saying the move set a new benchmark on drug pricing.

"It is as much as we could reasonably expect of one company on their prices," said Oxfam senior policy adviser Sophia Tickell.

However, the charity also kept up the pressure by calling on the firm to take a lead in pushing for change to world patent regulations.

"GSK continues to maintain that World Trade Organization patent rules are not an issue in access to drugs in poor countries. Oxfam research shows that they in fact lead to high drug prices way beyond the reach of millions of people in the world's poorest countries," said Tickell.

World patent rules will be discussed at an unprecedented meeting of World Trade Organization members in Geneva on June 20.

Oxfam spokesman Michael Grainger told CNN that although GSK's policy decision could go a long way in terms of the price of drugs, the company would need to take the rest of the industry with it.

"Without a fundamental change in patent rules, countries would continue to depend on the whim of company policy," he said.

While making concessions on a wide range of drugs, GSK insisted that the pharmaceutical industry could not be held responsible on its own for delivering healthcare in the developing world.

GSK's Garnier said the industry could "play an important role" but it did "not have the mandate, expertise or resources" to act unilaterally.

He called on all sectors of society including governments, international agencies and the private sector, to "work together in new kinds of partnerships, backed by significant funding."

He also said he supported U.N. Secretary-General Kofi Annan's call for a large-scale global fund to fight AIDS and other disease.

Image problems

The measures announced by GSK may go some way to improving the image of the industry which has been scarred in recent months, for example by the court case against the South African government when it tried to stop it importing cheaper generic versions of patented drugs.

The case, which involved 39 pharmaceutical companies, including GSK, proved to be one of the worst corporate PR disasters.

South Africa, with more HIV and AIDS sufferers than anywhere else in the world, proved to be the wrong country to take to court over the issue of intellectual property rights.

The case was dropped, but not before the international opinion had been left with the impression that the industry was more concerned with protecting its patents than in the health crisis in developing countries.

Title: Uganda's deal with drug firms

Author: Jim Boulden

Source: CNN Business

Date: June 7 2001

Web site:
<http://edition.cnn.com/BUSINESS/programs/yourbusiness/stories2001/aids.uganda.2/>

Uganda's deal with the drug firms

KAMPALA, Uganda (CNN) -- About one and a half million people in Uganda have HIV or AIDS.

That's actually a lot less than projections of just a few years ago as Uganda has cut the rate of new HIV/AIDS cases by two thirds in the past 10 years through an aggressive education campaign.

However, HIV/AIDS still ravages the area around Kwanda, one of the first places to be struck by the virus.

The local carpenter has stopped making furniture altogether. He is too busy building 35 coffins a week.

About 10 percent of Ugandans have HIV/AIDS. Nearly one million Ugandans have already died from the disease, but while images of the sick and dying in Africa abound, there are a lucky few who have had access to life-extending anti-retroviral drugs or ARVs.

Reverend Gideon Byamugisha of the Church of Uganda told CNN that he nearly died in 1998.

"I shouldn't be speaking to you. I should be dead. Because my doctors had written me off until some good samaritan came to my rescue and began sending this medicine," he said.

However, the vast majority of infected Ugandans cannot afford the combination of drugs that could save their lives, even after the government and the big drug companies struck a deal in December via the United Nations, making ARVs 90 per cent cheaper than in Western countries.

The average price for a combination of ARVs is now \$700-\$1,300 a year.

The average Ugandan makes less than \$2 a day.

South Africa and Kenya have fought the drug firms to bring down the cost, but Uganda decided instead, like a handful of other countries in sub-Saharan Africa, to

sign a deal with the international pharmaceutical companies, through the United Nations, to buy cheaper drugs.

Uganda's President Yoweri Museveni told CNN that the drug companies were "business people."

"They are in business because they make some profit. First, they recover what they put in the development then they make a profit. How can you reasonably argue with them to produce these drugs at a loss to themselves? This is not common sense," he said.

Drive to lower prices

But many doctors and non-governmental organisations (NGOs) want drug companies to cut prices further.

Doctor Peter Mugenyi, director at the Joint Clinical Research Centre in Kampala, said: "A huge number of people continue to die while treatment is available, is cheap to produce and yet certain groups of people are hanging onto this treatment because they must exact their pound of flesh while people are dying."

Doctor Mugenyi runs a clinic that sells ARVs to some 3,000 patients.

Last year, Cipla, an Indian-based drug manufacturer, started to sell cheaper versions of Western AIDS drugs. These generic versions of the drugs have upset Western pharmaceutical companies who accuse Cipla of violating drug patents.

But Uganda's doctors have no problem importing the generics to bring costs down further.

"In response to the cheaper versions of these drugs, we have had a huge rise in the number of patients. We have had to hire new staff to cope with the increased number of patients who have come simply because for the first time in their lives they are able to afford these life-saving treatments," said Doctor Mugenyi.

It was pressure from international bodies like the UN and the presence of generics that led the drug companies to cut their prices in parts of Africa.

Pharmaceutical giant GlaxoSmithKline says the company now sells its drugs at cost price in Uganda.

"A substantial amount of money is required to tackle HIV/AIDS and as an industry we have done our bit: lowering the price of products and making sure the medical community is educated on HIV/AIDS products. Yes, obviously there is a need for more funding, but the industry, or Glaxosmithkline, has done its bit," said the firm's representative in Uganda.

With prices unlikely to fall much further, the international community is looking for ways to pay for ARVs in sub-Saharan Africa. There is widespread agreement here that Africa can contribute a tiny portion to a larger fund.

"We can make a contribution if it's an international effort...Uganda can raise \$5 million and put it in that bag. It is not that we don't have money at all," said President Museveni.

International effort

NGOs and Western governments are also under pressure to increase their contributions to a U.N.-sponsored war chest to fight AIDS, malaria and TB.

Campaigners say the West needs to raise \$10-20 billion a year to start treating millions of Africans.

"With a great deal of hard work, with a tremendous amount of goodwill, with strong donor support, with strong support from the pharmaceutical companies, we may be able to get to around a million people in treatment within two or three years in Africa. That could rise to three to five million people by the fifth year," Jeffrey Sachs, director of international development at Harvard University told CNN.

Individual companies in Uganda and indeed across Africa could become big beneficiaries of this push. Lower drug prices will save their health plans millions and millions of dollars and enable them to offer these life-extending drugs to their employees.

One such company is Kakira, a sugar firm in eastern Uganda. With more than 6,000 employees and some 25,000 dependents, Kakira is one of Uganda's biggest employers.

It estimates that 10 percent of its employees are probably HIV positive. The company cannot afford to cover employees with AIDS.

What money it does spend goes on preaching prevention in the villages where the employees live.

The company would like to provide ARVs.

"They are very, very expensive in the marketplace. If the initiatives bring the price down...then we certainly will look at it," said Kakira's Richard Orr.

But until companies, governments and the drug firms find a way of making the drugs more affordable, HIV sufferers like mother-of-four Fausta Katabaira will continue to plan for her death.

"Seeing death coming to you and you have nothing to do. It's very unfair. We are human beings, when there are drugs and you cannot get to them," said Katabaira.

While the education campaign continues to spread the message of prevention, places like the Mildmay AIDS Clinic outside Kampala provide comfort to sufferers such as day care for infected children.

Staff at the clinic wait for donations to move their patients, one at a time, onto ARVs.

Title: Affordability, Availability and adaptability of AIDS drugs in developing countries: An on going challenge

Author: Stanley Kurtz

Source: LifeSiteNews

Date: September 25, 2006

Web site: <http://www>.

Affordability, Availability and Adaptability of AIDS Drugs in Developing Countries: An On-going Challenge

August 1, 2008

MSF's Campaign for Access to Essential Medicines first published a report on AIDS drug prices in 2001, in response to the lack of transparent information available for treatment providers to be able to make informed purchasing decisions. MSF, along with others providing HIV/AIDS treatment in developing countries, continue to struggle with affordability, availability and adaptability of antiretroviral drugs (ARVs). Now in its 11th edition, 'Untangling the Web of Antiretroviral Price Reductions' provides a window into the evolution of ARV prices since 2001.

Karen Day, Pharmacist Coordinator for MSF's Campaign for Access to Essential Medicines, provides an overview of some of the key issues in this years' report:

What does treating a patient with ARVs cost these days in developing countries?

Well, the most affordable first-line antiretroviral fixed-dose combination (3TC/d4T/NVP) now costs \$87 per patient per year. We've come a long way since 2001, when this cost more than \$10,000 per year, before generic producers started making ARVs – that's more than a 99% price reduction. But a real challenge that treatment providers, including MSF, are facing is high prices for newer ARVs.

HIV/AIDS is a disease that requires life-long treatment and people need to be able to have access to newer drugs to give them alternatives when they experience the side effects of their drugs, or when they develop drug resistance. Resistance is something that will inevitably develop, even if people take every single pill correctly. For these situations, we need access to new, more potent, and less-toxic drugs.

Can you give an example of the price increase you see for people who need to switch because of side effects? And how common are these side effects?

The drug stavudine (d4T), which is one of the components of the most commonly used ARV fixed-dose combination in developing countries, is associated with many side effects, which are quite common. In one of MSF's AIDS projects in Rwanda, almost

one in every six people on stavudine had to change their regimen due to toxicity. In 2006, the World Health Organization recommended that treatment providers move away from this drug to less-toxic regimens, based on either zidovudine (AZT) or tenofovir (TDF). But this has considerable price implications, ranging from double, at best, for AZT-based regimens, to up to 11 times for TDF-based regimens, in countries that cannot access generic versions because of patent protection. We need the prices to come down, but for this to happen, we need more manufacturers to enter the market, creating the competition that drives prices down.

And what about patients who need newer drugs because of resistance?

For patients who need a 'second-line' treatment regimen, the price jump is a lot greater. The increase ranges from nine-fold to up to 17-fold in some 'middle-income' countries where the drugs are patented and treatment providers must buy the product from the originator company. And the need for second-line regimens will continue to increase. In MSF's longest-running AIDS project, in Khayelitsha, South Africa, 22% of patients on treatment for five years needed to be switched to a second-line drug combination. We desperately need more affordable newer medicines to be available in developing countries.

Pharmaceutical companies offer price discounts for developing countries, don't they?

Yes, but when new drugs enter the market, the companies generally have the monopoly and can control the market by dictating which countries can access the drug and at which price. Experience has shown that the discounts these companies offer are simply not big enough to make a difference.

Competition among multiple producers is the tried and tested way to bring prices down, but patents can stand in the way of allowing generic producers to enter the market. India, for example, didn't grant pharmaceutical patents until 2005, and therefore has been one of the key countries where affordable medicines have been

produced. In fact, MSF buys more than 80% of the AIDS drugs it uses from Indian manufacturers and the country has been called the ‘pharmacy of the developing world.’

So why aren’t there affordable generic versions of the newer drugs for which there is a growing need?

Because more and more of these newer drugs are being patented in India, despite the fact that the country has a very strict law in terms of what does and does not deserve a patent. So this means that generic manufacturers will no longer be able to produce affordable versions of drugs unless the company agrees to voluntary licenses with generic manufacturers, or the government decides to override a patent with a legal mechanism in patent law called a ‘compulsory license,’ which allows another entity or entities to produce the drug against the payment of a royalty. Another way around this is through pooling patents and managing patent rights collectively, such as the recent proposal the drug purchasing facility UNITAID is moving forward with. This will help bring prices for newer drugs down through increased competition, and lead to the development and production of pediatric formulations and the combination pills we need to simplify treatment for patients.

And what are the trends with AIDS drugs for children?

Unfortunately, children continue to be an afterthought when it comes to producing appropriate formulations of medicines. Of the 22 ARVs approved by the U.S. Food and Drug Administration, eight are not approved for use in children and nine do not come in any kind of pediatric formulation. And when versions for kids do exist, they are often not adapted for use in resource-limited settings, meaning they are powders requiring reconstitution with water, or syrups, both which may need refrigeration, for which access can be limited in developing countries. In addition, the bitter taste of some formulations makes dosing children quite a challenge.

Generic manufacturers have actually been at the forefront of developing and producing adapted three-in-one combination tablets for kids, and several do now exist. But it’s a sad fact that it has taken six years longer to get such a tablet combination for kids than it did for adults. There really needs to be more effort put in to addressing pediatric AIDS, but because in the West pediatric AIDS has nearly disappeared, there is not much of a market incentive for pharmaceutical companies to invest in it.

But the bottom line is that if prevention of mother-to-child transmission programs were implemented more successfully in developing countries, as they are in the West, we wouldn’t still be seeing the alarming infection rate among children anymore. There is an urgent need to address this.

And what about some of the newest AIDS drugs that have come out recently?

There have been some significant advances in the development of new drugs that attack the HIV virus in new ways. This really offers people living with HIV/AIDS many more treatment options. The trouble is, few of these newer drugs are developed to address the specific needs of patients in developing countries, such as women of childbearing age, children, and people who need to be able to take drugs for other conditions such as tuberculosis or malaria at the same time. This is a real problem, and there needs to be change much earlier in the drug development process, so we don’t have to wait years and years after such drugs become available in the West for there to be formulations that people in developing countries can use.

The companies that are producing these new drugs furthermore have not even provided prices for developing countries, which shows you how far away we still are from being able to get these drugs to people in resource-limited settings. The access gap still remains huge between people in wealthy and developing countries. And the lack of a specific research and development agenda for AIDS in the developing world is a growing problem.

Title: Funding for AIDS drugs in jeopardy as global financial crisis hits health sector.

Author: Stanley Kurtz

Source: LifeSiteNews

Date: September 25, 2006

Web site:
http://www.unaids.org/en/KnowledgeCentre/Resources/FeatureStories/archive/2009/20090428_WB.asp

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The current crisis in financial markets and the world economy is having a profound effect on both governments' global development commitments and national resources. Households already most vulnerable to poverty, risk further impoverishment as unemployment rises and incomes are reduced. There is widespread concern that progress in health and education will be severely undermined.

This is the second in a series of articles on the how the economic downturn impacts people already affected by HIV and how investment in sustainable financing is critical for global AIDS and development responses. The World Bank has just published a report that explores these issues in depth.

The worldwide economic downturn may already be causing hardship in supplying life-saving drugs to people with HIV, according to a new World Bank report which highlights the clear and rising human cost of the current financial climate.

Averting a Human Crisis During the Global Downturn: Policy Options from the World Bank's Human Development Network, reports preliminary findings from a survey in 69 countries showing that 8 countries already face shortages of antiretroviral (ARV) drugs or other disruptions to AIDS treatment. The survey, conducted by the

World Bank, UNAIDS and the World Health Organization last month also contends that, in total, respondents in 22 countries in Africa, the Caribbean, Europe and Central Asia, and Asia and Pacific expect the crisis to impact treatment programmes over the coming year. Together, these countries are home to more than 60 percent of people worldwide on ARVs.

This is a serious development. Despite rapid recent expansion in the numbers of people receiving treatment, two thirds of those in need of such drugs still do not get them. And unmet need is growing faster than treatment access is expanding. The global crisis seems likely to exacerbate the situation.

"This new report shows that people on AIDS treatment could be in danger of losing their place in the lifeboat," says Joy Phumaphi, the World Bank's Vice President for Human Development and former Health Minister for Botswana.

Prevention programmes in jeopardy

“ We cannot afford a ‘lost’ generation of people as a result of this crisis. It is essential that developing countries and aid donors act now to protect and expand their spending on health, education and other basic social services and target these efforts to make sure they reach the poorest and most vulnerable groups. ”

Joy Phumaphi, the World Bank's Vice President for Human Development

HIV prevention programmes are also in jeopardy. The report states that survey respondents in 34 countries, where 75 percent of people with the virus live, expect prevention programmes for their key populations at higher risk (including sex workers and people who inject drugs) to be

adversely affected as they are marginalized and tend to get lower priority than say pregnant women and children.

The world has made an international commitment to providing universal access to HIV prevention, treatment, care and support services to those in need by 2010. The global scale up towards this key goal, which has been gathering momentum, may well be threatened by what the report calls “these extraordinarily challenging times for the global economy.”

In *Averting a Human Crisis During the Global Downturn*, the Bank is encouraging countries which depend extensively on external donor AIDS financing to identify impending cash shortages as far as possible in advance, and to liaise with the Bank and other partners to help to mobilize 'bridge financing' that prevents interruptions to AIDS treatment. At the same time, the Bank warns that maintaining and expanding effective HIV prevention programmes during the current crisis is essential to guard against a resurgence of new infections.

Potential cuts in health and education financing

The World Bank is concerned that the downturn will lead to cuts in health and education financing across the board, not only in the sphere of AIDS. The report also shows how previous crises have forced developing countries to cut back on spending in these areas. Evidence from past downturns in Argentina, Indonesia, Thailand, and Russia shows that governments were forced to cut health services as a result of shrinking budgets and that returning health spending to pre-crisis levels took up to 10-15 years.

”We cannot afford a ‘lost’ generation of people as a result of this crisis,” Phumaphi contends. “It is essential that developing countries and aid donors act now to protect and expand their spending on health,

education and other basic social services and target these efforts to make sure they reach the poorest and most vulnerable groups.”

In support of this strategy, on 24 April the World Bank stated that it was mobilizing up to US\$ 3.1 billion this year in health financing to help poor countries battle threats to their social services during the global crisis. This effectively triples Bank support from US\$ 1.0 billion in 2008 and will be used to strengthen health systems in poor countries, boost their performance in preventing and treating communicable diseases, and improving child and maternal health, hygiene and sanitation.

The Bank also said it was doubling its education financing this year in low- and middle-income countries to US\$ 4.09 billion.

This report draws heavily on ongoing collaborative work by the World Bank, UNAIDS and WHO which will be released soon in a joint publication. Information was collected by agency representatives working closely with the National AIDS authorities in 69 low- and middle-income countries, which together include most people on treatment in the developing world. Preliminary conclusions are referenced here for consideration at the 2009 IMF World Bank Spring Meetings in Washington DC.

Web site:
<http://www.hrw.org/en/news/2001/11/06/wto-summit-dont-undercut-aids-drug-access>

[WTO Summit: Don't Undercut AIDS Drug Access](#)

November 6, 2001

AIDS is already tearing these countries apart. They shouldn't face sanctions from the developed world on top of that.

Joanne Csete, Director of the HIV/AIDS program of Human Rights Watch

Trade ministers at the upcoming WTO summit in Doha, Qatar should abandon threats of sanctions against countries trying to obtain medicines for health emergencies such as HIV/AIDS, Human Rights Watch said today. The WTO summit will take place from November 9 to 13.

The part of the WTO agreement dealing with patents, known as TRIPS (Trade-Related Aspects of Intellectual Property Rights), allows exceptions to patent rules in the case of a national emergency or where a product will have non-commercial uses. Fifty-developing countries and Norway are urging the WTO ministers in Doha to make a pledge not to impede legitimate use of emergency exceptions to TRIPS. In negotiations leading up to the Doha summit, the U.S. and a number of other countries that are home to the major multinational pharmaceutical companies have been intransigent in opposing this pledge.

The United States has also bilaterally threatened sanctions against several countries with severe AIDS problems, such as Thailand, South Africa and Brazil.

"AIDS is already tearing these countries apart," said Joanne Csete, director of the HIV/AIDS program at Human Rights Watch. "They shouldn't face sanctions from the developed world on top of that."

Approximately 9,000 persons a day die of AIDS, the large majority in countries where anti-retroviral drugs are unavailable or unaffordable. More than 22 million people

have died of AIDS, about 18 million of them in sub-Saharan Africa.

The office of the U.S. Trade Representative Robert Zoellick announced last week that instead of the 53-country proposal reinforcing the health emergency exceptions in TRIPS, it would support a counter-proposal that would give "least developed countries" more time until they are required to be fully compliant with TRIPS and would impose a five-year moratorium on initiation of WTO complaints against countries seeking TRIPS exceptions.

Csete noted that the U.S. proposal is a step in the right direction but would cover only the poorest countries and would not include others such as Brazil and South Africa that have capacity for domestic production of generic drugs. She urged the United States not to use bilateral threats and sanctions when the global system allowed exceptions that Washington opposed.

The United States, Canada, Japan and the United Kingdom have been granted exceptions to TRIPS and the pre-WTO trade rules many times to protect their own interests in areas as wide-ranging as pharmaceuticals, computers, software, and biotechnology innovations. Canada recently said it would seek a compulsory license — a license to produce and import the generic version of a brand-name medicine — to ensure its stock of anti-anthrax drugs. New Zealand, Australia and Italy have also used compulsory licensing as an antitrust measure.

In contrast, no low-income developing country has succeeded in obtaining a compulsory license for generic AIDS drugs.

The United Nations Development Programme's "Human Development Report 2001" attributes this disparity to threats from Europe and the United States of trade sanctions, loss of foreign direct investment, or litigation against low-income countries hoping to obtain compulsory licenses. Earlier this year, for example, the U.S. threatened to put Thailand on "priority watch" — a disadvantageous trade status — in response to the Thai government's attempt to shorten the waiting period for production of generic drugs in Thailand after the release of their brand-name counterparts. (An estimated 750,000 persons in Thailand suffer from AIDS.) A similar U.S. action against Brazil, brought through the WTO, was dropped this year only in the face of heavy international pressure against the case.