POLICY FORUM: PUBLIC HEALTH

HIV/AIDS Treatment for Millions

Hans P. Binswanger

Treatment of HIV/AIDS involves treatment of opportunistic infections, prophylaxis, and antiretroviral (ARV) therapy. ARV therapy suppresses the virus and enables patients to live for many years. Three or more ARV drugs may be used simultaneously to reduce viral resistance. Total treatment costs include not only drugs, but complementary costs, including doctors fees, tests, and psychosocial support. In the United States, total costs vary between $12,000 and $20,000 per year.

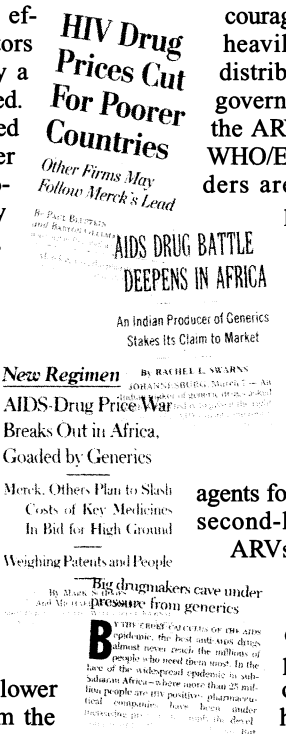
A price war between generic manufacturers and the pharmaceutical industry has at last led to sharp reductions in drug prices (*1*). Several triple-therapy regimes can be provided (combining drugs from Glaxo-SmithKline, Merck & Co., and Bristol-Myers Squibb Co.), each for less than $1330 per year. The World Bank has used an estimate of $500 for complementary treatment costs in Africa, but this appears very high (*2*). Even with these costs, the new offers would imply a total treatment cost in Africa of around $1800 per year. Cipla and Hetero Drugs, generic manufacturers from India, have offered to sell the drugs for one triple-therapy regime at $350 to Doctors without Borders and at $600 dollars to governments and others, further lowering total treatment cost to the range of $850 to $1150.

These are extraordinary developments that are well worth celebrating. However, many issues must be resolved.

Access for Those Who Can Pay

Before these announcements, Uganda's current pilot program had been making ARV treatment available to wealthy and powerful individuals able to pay $6000 to $8000 per year. If treatment costs fall to between $600 and $1200 per year, coverage could rise from the current 1000 people to 50,000 or 3.8% of their currect population of HIV patients (*3*). The cost of additional treatment infrastructure is estimated at $3 to $4 million. Africa has around 25 million infected people, and it is hard to estimate how many would be able to pay the new reduced price. If only 5% could afford to pay, that would be 1.3 million people. If health insurance covered another 5%, over 2.5 million could be treated. Not all of them would be reached, because many do not know that they are infected, others can safely delay treatment until their CD4 cell count falls to around 350 (*4*), some are not near a doctor, and some cannot tolerate the side effects. Allowing for these factors would still mean that nearly a million Africans could be treated.

The "infrastructure" required includes trained doctors, other health professionals, and laboratories to do the necessary tests. Although substantial, this is not more than for tuberculosis (TB) treatment, and far less than the hospital and laboratory infrastructure required to treat the complex opportunistic infections of late-stage AIDS. Indeed in the United States, the shift to triple-therapy led to a sharp reduction of hospital use and, despite the enormous high prices of the drugs, to lower total treatment costs per HIV patient (*5*). Of course, new demand for treatment created by the lower prices will initially overwhelm the existing infrastructure, but it will create strong private-sector demand for clinics, laboratories, doctors, pathologists, and other medical staff to invest in training and equipment. These investments may therefore not have to be financed from the meager fiscal revenues of poor countries.


HIV Drug Prices Cut For Poorer Countries

Other Firms May Follow Merck's Lead

AIDS DRUG BATTLE DEEPENS IN AFRICA

An Indian Producer of Generics Stakes Its Claim to Market

New Regimen

AIDS-Drug Price War Breaks Out in Africa, Goaded by Generics

Merck, Others Plan to Slash Costs of Key Medicines In Bid for High Ground

Weighing Patents and People

Big drugmakers cave under pressure from generics

A major bottleneck could arise because the pharmaceutical companies intend to restrict the low prices to governments, firms, or nongovernment organizations that can control drug distribution to the end user. The companies fear that drugs could leak from low-cost countries and be transformed into parallel imports to circumvent the higher prices being charged in developed countries. Many other industries with high overhead and low marginal costs, such as the airline and hotel industries also practice "segmented pricing" as their profit-maximizing strategy—they charge different prices to different customers in the same plane or hotel to attract those who would otherwise not come. Airlines and hotels cannot prevent business people from taking advantage of low excursion fares. Instead, they structure the fare rules so as to discourage it. Drug companies should not, therefore, hope for a system with zero parallel imports. They will need to find ways to minimize leakage in more open distribution systems.

The most important obligation of governments now is to get out of the way of those able to pay. They must quickly issue licenses and regulations for ARV drugs. They can exempt the medication from import duties, help manufacturers to access domestic markets and distribution, and discourage or prohibit the re-export of heavily discounted drugs. If drug distribution systems function well, governments can offer to distribute the ARV drugs. UNAIDS, UNICEF, WHO/EDM, and Doctors without Borders are providing information on prices and sources of supply (*6*). They have also started to provide information on ways to accelerate drug certification and on options for increasing competition from generic drugs. UNICEF, the World Health Organization (WHO), and others who act as procurement and distribution agents for vaccines, essential drugs, and second-line TB drugs could include ARVs. The World Bank and other agencies can help finance infrastructure and encourage the exemption of drugs from import duties. As in the case of other essential drugs, they can help establish and finance the first supply of drugs for a "revolving ARV drug fund." Sale of the initial stock of medications at full cost would then provide the money to finance the replacement stock.

Insurance programs of most companies and organizations (including the United Nations) still do not cover ARV treatment for employees recruited in their offices in the developing world and for their immediate family members. The Ivorian Power Company, Anglo American of South Africa, Debswana of Botswana, and the World Bank have initiated such insurance coverage or announced that they will do so. The International Association of Physicians in AIDS Care in South Africa is developing an insurance program that includes ARV coverage for a broad range of clients. Countries

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should pass legislation to compel insurance programs to cover ARV medication on grounds of nondiscrimination.

Access for Those Unable to Pay

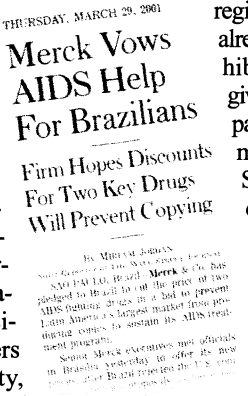
Even with lowering of drug prices, the large majority of patients will be unable to afford treatment. HIV/AIDS places a huge burden on governments of poor countries for prevention of the disease, for help to families and orphans, and for patient care. For Africa, the total cost of these programs would be around $3 billion per year. Governments and citizens of the developed countries will have to finance large-scale targeted programs for those unable to pay in very poor and/or highly affected countries. Even if the cost rose to $7 billion per year, as has been estimated (*7*), this would represent the price of a movie ticket with popcorn if every person in the developed world contributed. Affordability is not the issue, rather it is willingness to pay.

Even for simple drug regimes, donation programs face much greater implementation challenges than making the drugs available to those able to pay (*8*). In addition to dealing with the inherent complexity of ARV treatment, targeted programs will have to be rationed, implying hard allocation decisions. Experience from countless other subsidized programs around the world leaves little hope for the ability of governments to make equitable choices on who to treat, or to do so in a fast and cost-effective manner (*9–11*).

Nevertheless, many efforts have been initiated. Boehringer Ingelheim is offering its drug nevirapine free of charge for a period of 5 years for the prevention of mother-to-child transmissions (MTCT) and is collaborating with the Elisabeth Glaser Pediatric AIDS Foundation. The first shipment was provided to Brazzaville in the Republic of Congo last October. The French Fonds de Solidarité Thérapeutique is providing ARV treatment to a handful of mothers whose children have benefited from MTCT treatment in several countries. Pfizer has agreed to provide diflucan to treat dangerous opportunistic fungal infections free to government clinics in South Africa. The first shipment of drugs has finally left at the beginning of March.

Thirty-two countries have expressed interest in participating in the UNAIDS drug access initiative. Under this initiative the Fonds de Solidarité of the Ivory Coast provides subsidized or free ARV medication to around 1000 patients. Last summer, the Bill and Melinda Gates Foundation, Merck, and the Republic of Botswana launched a program to accelerate the prevention, treatment, and care of HIV-related illnesses. Bristol-Myers Squibb has started its 100 million dollar "Secure the Future" program for South Africa and four more Southern African countries. Launching these programs has involved complex, time-consuming consultations and negotiations among a range of partners, including governments. Bolder approaches are needed if patients in the nearly 80 poorest countries in the World are to be reached.

Another source is small associations of people living with HIV/AIDS in North America and France, who collect unused drugs earmarked for patients who have stopped or switched treatment. These recycled drugs are collected from clinics, doctors, and individuals; inspected and prescribed to patients by collaborating physicians. The groups currently cover over 600 patients and, together with their doctors, have already overcome infrastructure constraints in more than 13 of the poorest countries. The receiving associations promote prevention and positive living among all their members and within the wider community, fight the stigma of HIV/AIDS, and provide psychosocial support for patients and their families (such as access to drugs for opportunistic infections, home-based care, nutrition, and emergency food supplies). They are more likely to be able to target the drugs fairly to those unable to pay than government-sponsored committees. With a minimum of oversight they could manage much larger drug donation programs cost-effectively.



THURSDAY, MARCH 29, 2001

Merck Vows AIDS Help For Brazilians

Firm Hopes Discounts For Two Key Drugs Will Prevent Copying

Can Drug Prices Fall Further?

Pharmaceutical companies charge high prices for patented drugs to recover high overhead costs for research and development and for clinical trials. Low marginal costs explain why generic drug producers (who currently pay no royalty to patent holders) can produce medicines very cheaply. Ciprofloxacin, an antibiotic used to combat bacterial infections including gonorrhea, is priced at $3.40 per tablet of 250 mg in the USA, where it is covered by a patent, but only at 5 cents per tablet in Colombia and Guatemala, where it is supplied by generic producers.

How can the generic drug manufacturers compete with patent holders without violating intellectual property rights? Under WTO rules, least developed countries need not be fully compliant with the new intellectual property right rules until 2006. Several ARV drugs such as AZT were patented before 1995 when WTO mandated product patents, and so can be produced legally without payment of royalty in a number of countries (*12*). When the time comes for these countries to fully protect intellectual property rights, they can take advantage of the Bolar provision, which allows generic producers to start stockpiling a patented drug and completing regulatory procedures for approval even before the patent expires. WTO rules are silent on parallel imports and permit compulsory licensing: Any poor country may allow a generic manufacturer to use a patent without the owner's consent. The third party is required to try first to get a license from the patent holder on reasonable terms, but this condition can be waived in cases of national emergency. However, the actual outcome will depend on the patent regime of each country. Some may already have enacted patent laws inhibiting generic imports or have given exclusive marketing rights to patent holders. Recently, the pharmaceutical company GlaxoSmithKline objected to the export of ARV drugs by Cipla to Ghana, and threatened them with litigation. A consortium of 39 drug companies is currently challenging the South African government in court on similar issues. Poor countries therefore need to frame their own patent laws to make maximum use of the flexibility offered by WTO regulations. They also need to ensure that drug importing and marketing in their countries are highly competitive.

Both routes to greater access—increasing access for those able to pay, or increasing donations—would benefit from further price reductions. If competition among and between generic drug manufacturers and the patent holders continues or intensifies, the prospects are bright.

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