
Access To Highly Active Anti-Retroviral Therapy (HAART) For HIV Infection In India

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Abstract

Background: Among millions of HIV infected individuals in India, few receive HAART as a result of high costs. Generic manufacture of drugs here has led to price reductions of HAART. Generic drugs impact multinational pharmaceutical companies' ability to reclaim their costs of research & development. The World Trade Organization's (WTO) Trade Related Aspects of Intellectual Property Agreement (TRIPS) requires patent protection for pharmaceutical inventions, preventing generic competitors from producing cheaper alternatives. Under certain provisions of TRIPS, Indian pharmaceuticals were able to manufacture low cost generic HAART until now. Recently, the Indian government passed a bill regulating pharmaceuticals to comply with TRIPS. Stoppage of generic drug manufacturing can diminish access to HAART for large numbers of HIV infected people. However, several other barriers can also decrease access to HAART.

Objective: The focus of this document is to analyze viable policy alternatives to generic drug manufacturing, an issue related to HIV therapy that is currently under debate.

Methods & Results: While evaluating a variety of policy options to improve access to HIV therapy, increased international aid to strengthen the health care system, expand screening of HIV infection, reinforce health provider & patient education thereby improving access to HAART is proposed. Bulk buying by governments to meet increased demand for HAART can result in competitive market pricing of HIV drugs.

The focus of this document is to analyze viable policy alternatives to generic drug manufacturing, an issue that is currently under debate. Policy options that improve access to HAART for HIV patients in India will be discussed based on a methodical approach to policy analysis proposed by Eugene Bardach (1).

PROBLEM DEFINITION & BACKGROUND

Of the millions of HIV infected individuals in the world, more than 90% live in developing countries of Africa and Asia. In India alone in year 2006, an estimated 5.7 million people have HIV/AIDS that is more than any other country in the world. Almost every state in India has reported HIV cases. (2)

Highly active antiretroviral therapy (HAART) has led to a dramatic decline in AIDS-related morbidity and mortality. (3) However, such advances in HIV therapy have not benefited those suffering from HIV/AIDS in the developing countries. (4) One of the important reasons has been the high cost of antiretroviral therapy (HAART). Although, more than 600,000 individuals in India are in need of antiretroviral

therapy, less than 30,000 are currently on HAART.

Generic manufacture of drugs in developing nations has led to price reductions of HAART and has made these drugs accessible to the poor patients suffering from HIV/AIDS. However there are several concerns among pharmaceutical companies and the medical community regarding the proper manufacturing and distribution of such antiretroviral drugs. According to the Pharmaceutical Research and Manufacturers of America (PhRMA), pharmaceutical companies depend on patents to protect their huge investments in new pharmaceutical inventions. Pharmaceutical companies incur enormous costs in the research and development of new drugs. Estimates show that it takes approximately 10-15 years and costs roughly \$800

million to introduce a new medicine to market. (5) While, generic producers do not contribute towards research into new drugs, they can produce low-cost drugs that are easily affordable. However, generic manufacturing would seriously impact the pharmaceutical companies' ability to reclaim their costs and reinvest in other research projects.

The World Trade Organization (WTO) developed an international agreement of patent protections for drugs across the world. This agreement called Trade-Related Aspects of Intellectual Property Agreement (TRIPS Agreement) requires patent protection for pharmaceutical inventions for a period of 20 years, preventing generic competitors from producing cheaper alternatives. (6) However, this TRIPS Agreement has some provisions that allow the delay of enforcement of TRIPS agreement for several years after initial application by a member country. As one of the first TRIPS member, India has made full use of these provisions to manufacture generic drugs disregarding patent regulations of TRIPS. However, India's utilization of provisions of the TRIPS agreement to manufacture generic HAART has certainly helped the people of India to access HIV/AIDS therapy at affordable costs. From January 2005, India will have to provide patent protection for medicines as part of its obligation under TRIPS. India's parliament passed a bill in March 2005 that changed the patent laws to prohibit the production of generic versions of patented medicines, including antiretroviral drugs. (7) Therefore, new HIV drugs discovered after 1995 will be sold in India at international prices unaffordable to Indian HIV patients. Also a recent proposal allows compulsory licensing of HIV drugs in countries only with capability to manufacture those medications, which certainly limits import of HIV medications to nations without this manufacturing capability. Due to emerging controversies concerning access to HIV drugs, the 2001 DOHA Ministerial conference was convened to specifically address the concern of public health among developing countries within the TRIPS agreement. This DOHA declaration formed provisions for an acceptable interpretation of the TRIPS treaty for member countries and recognized that intellectual property rights issues cannot be discussed separate from public health concerns. However, several other barriers to an acceptable HIV Drug pricing policy exist in developing countries.

National governments, international voluntary organizations and other bilateral donors and foundations have pledged just over US\$ 2 billion towards antiretroviral treatment access by

the year 2005. This aid falls short by US\$ 3.5 billion with large variations at the country level. International aid has declined disproportionately compared to the increase in HIV disease burden in developing countries like India where more than 4 million HIV infected people live today. Even though financial resources are rising, in many heavily affected countries several barriers prevent effective spending of the money. These blockages include lack of provider and institutional resources, social stigma and discrimination, societal commitment and inconsistent funding processes of the international donor community. (8)

The major stakeholders in HIV Drug pricing policy are:

1. **Pharmaceutical companies manufacturing HAART:** The major multinational pharmaceutical companies in the US and UK such as Glaxo, Ranbaxy and Bristol Myers Squibb spend billions of dollars on research and development of HAART. Under the TRIPS agreement new drugs are protected by patents for a period of 20 years. HAART is marketed at subsidized prices by these companies to developing countries to enable them to afford such treatment.
2. **Indian Pharmaceutical Companies:** Indian companies although do not have sufficient research and development capabilities for HAART manufacturing, have utilized a process called reverse engineering to manufacture low cost generic HAART. Indian companies have also been able to export such low cost HAART to other countries such as South Africa for control of HIV/AIDS.
3. **Indian Government:** Since 1970, The Indian Patent Act safeguarded the rights of Indian Companies to manufacture generic versions of patented drugs in India. In view of the TRIPS agreement, the Indian government is obliged to change its patent laws in 2005. India's parliament passed a bill in March 2005 that changed the patent laws to prohibit the production of generic versions of patented medicines, including antiretroviral drugs. This will result in restriction of generic drug manufacturing in India as well as export of HAART to the African countries with high HIV/AIDS prevalence. The Indian government is charged with the responsibility of improving the health care infrastructure, form a National Health Initiative against AIDS and provide an adequate health care framework to screen, diagnose and treat HIV infected patients.
4. **Developed Countries Governments:** Funding for the global fight against AIDS is mostly from countries such as

USA and UK. These governments have been supporting the enforcement of TRIPS agreement in all developing countries that can curb uncontrolled generic HIV drug manufacturing.

5. World Trade Organization: The WTO enacted the TRIPS treaty in 1995 to control generic drug manufacturing throughout the world. There are 142 members participating in TRIPS at this time. Also, the DOHA agreement by its member countries recently reinstated the fundamental concern for public health despite patent protection laws.

6. HIV/AIDS patients in India: This group forms the most important stakeholder in HIV Drug pricing policy in India. The fate of millions of HIV infected individuals depends on their affordability to HAART. Less than 5 % of all HIV infected patients in India receive HAART. With growing incidence of HIV among low risk population through heterosexual contacts, there is an urgent need to provide HAART at affordable cost.

7. Health Care providers in India: Health care providers require training and education in proper use of HAART as it is associated with both benefits as well as risk of serious side effects during therapy. Health care officers at the primary health care center level must be utilized to screen and treat HIV infected individuals. They should be able to offer counseling and education to the local public regarding the need for treatment and prevention of HIV.

8. HIV/AIDS activists: Several activist and human rights groups such as Oxfam, Health Gap, and Doctors without Borders have written, voiced and argued their concerns regarding need for HIV therapy at affordable pricing in developing nations. Other methods of raising awareness among governmental authority include letters addressed to government leaders by AIDS/HIV activists as well as detailed websites with information on trends in HIV/AIDS in developing countries.

9. Pharmaceutical Research and Manufacturers of America (PhRMA): According to PhRMA's position on intellectual property, "patents protect the investments of pharmaceutical companies in R & D that usually takes up to 15 years and costs \$800 million on average to market any new medicine. If other companies could simply copy the drugs immediately, offering generic versions at a reduced price, this would seriously impact the pharmaceutical companies' ability to regain their costs and reinvest in future projects." (6)

ALTERATIVE POLICY OPTIONS

Alternatives to generic drug manufacturing have been suggested that may enable better access to HAART by the needy in developing nations.

1. Government-Pharmaceutical company partnerships: Pharmaceutical companies and developing countries can work together to purchase huge quantities of essential drugs. The combined purchasing power of all these countries may lead to price reductions allowing wider access to HAART.
2. Low cost HAART: Pharmaceutical companies can reduce the prices of their patented HAART drugs and improve access to them among the needy patients in the developing world. Such an option is limited by quantity of products that can be subsidized as well the period for which this will be in effect. Further, it is feared that the health care of HIV patients in these countries will become dependant on support of the pharmaceutical industry.
3. Compulsory licensing: Compulsory licensing is a legal provision within TRIPS that allows manufacturing of generics at competitive prices by copycat pharmaceutical companies. Despite competitive pricing of HAART, it could still be unaffordable for developing nations.
4. International funding: Although several barriers to access of HAART exist in the developing world, lack of funds to improve health care infrastructure and delivery above all is a major contributing factor.

OUTCOME DESIRED

The main outcome expected due to the HIV/AIDS Drug Pricing policy is to enable availability of HIV drugs in India at affordable costs. However, one would like to achieve this outcome under a fair cost reimbursement scheme for the US pharmaceutical companies who invest in research & development (R & D) of such high cost drugs. The following are the specific outcomes desired from any policy that addresses these issues.

- A. Availability of HIV drugs to HIV patients in India at affordable cost (Best outcome)
- B. Enforcement of TRIPS or other agreements among Indian companies and world market
- C. Better R & D in HIV treatment

EVALUATIVE CRITERIA

Effectiveness: Firstly, it would be interesting to know as to

how many additional HIV infected patients “in the real world case scenario” will be able to receive treatment as a result of the new pricing policy options. Another important clinical effectiveness measure of any option utilized would be to study improvement in mortality, opportunistic infection rates or surrogate markers of HIV progression such as CD4 cell counts or Viral loads among population samples in different states in India who will receive the HIV drugs as a result of the new pricing policy options. It would also be interesting to evaluate the effectiveness of the Policy options in enforcement of TRIPS or other agreements among Indian pharmaceutical companies by periodically monitoring their compliance with TRIPS.

Efficiency: In regards to cost of HIV drugs under the new pricing policy, one would be keen to know as to who benefits from the cost control. Is it the patients, the local society, the Indian pharmaceutical companies or the government and how does it affect R& D among US pharmaceutical companies? Will cost control options using the new pricing policy lead to direct money saving, or indirectly affect on spending for health care in general due to decreased health care utilization by those receiving the drugs or other indirect benefits of improvement in health status of society with productive healthier individuals.

Equity: How will the new policy alternatives affect the HIV-infected individuals' right to affordable health care? While adopting the alternatives of the pricing policy, who pays for the cost of production of the drugs? Is it the wealthier nations or pharmaceutical companies in such regions or is it the poorer third world nations or those pharmaceuticals that produce generic drugs? In other words should there be international solidarity or social justice or a market driven pricing policy. Who accepts responsibility for the health status of HIV infected individuals in India – the patient, the local community or nation, the local drug companies or US companies or the international community? How do the pricing policy options tackle this question of responsibility?

Legality: Will the new pricing policy components lead to violation of rights of the stakeholders such as patients, local or US pharmaceutical companies? What international legal repercussions can occur if the TRIPS agreement or any agreement is enforced under the new pricing policy?

Political acceptability (political feasibility): Are the new policy options acceptable to the stakeholders namely the patients, the physicians, the pharmaceutical companies in India or US? Is there the political will and stability to accept

and implement the policy options with the least amount of resistance? Will the budgetary, political and market systems in India provide an opportunity to the new policy options to be acceptable and effective?

Robustness and improvability (administrative feasibility): What are the resources (human, financial and time) required to implement the new pricing policy options? Are these new policy alternatives adaptable to the current users of drugs and the current system of pricing and thus survive the test of time? Are the new policy options modifiable or feasible technically in the current market environment?

PROJECTED OUTCOMES & TRADE-OFFS

All policy alternatives are ranked based on evaluative criteria in a ranking matrix given below. (Table1) These alternatives are chosen to achieve the projected outcome namely, to improve availability of HAART to HIV infected patients in India at affordable cost. All policy options suggested in the ranking matrix have trade-offs as suggested by low scores for different criteria. The scores of 1 to 3 (1 =poor; 2= moderate; 3=better) denote the degree to which a specific alternative satisfies particular evaluative criteria. The trade-offs are the least for the International aid option (score 13/18) and the most for Compulsory licensing option (score 6/18)

Figure 1

Table 1: Ranking matrix of Alternatives illustrating the outcomes and trade-offs with respect to standard evaluative criteria.

| Criteria | Option 1 | Option 2 | Option 3 | Option 4 |
|----------------------------|---------------------------|----------------|----------------------|-----------------------|
| | Govt-Private partnerships | Low cost HAART | Compulsory licensing | International funding |
| Effectiveness | Poor | Moderate | Poor | Moderate |
| Efficiency | Moderate | Poor | Poor | Moderate |
| Equity | Poor | Moderate | Poor | Better |
| Legality | Better | Moderate | Poor | Better |
| Political Acceptability | Poor | Better | Poor | Moderate |
| Administrative feasibility | Poor | Moderate | Poor | Poor |
| Total Score | 9/18 | 12/18 | 6/18 | 13/18 |

POLICY RECOMMENDATION AND RATIONALE

Goal: To improve availability of HAART medications to HIV infected patients in India at affordable prices. **Policy recommendation:** Increase in International Aid to India to improve structure and function of regional health care system to enable screening, diagnosis of HIV infection and administration of HAART.

International Aid has declined disproportionately compared to the increase in prevalence of HIV disease in developing countries. Lack of finance is now a serious barrier in the progress against AIDS. Even though World Bank, WHO and other philanthropic organizations provide financial assistance, the HIV pandemic in India remains out of control. This is partly due to the enormity of the disease burden affecting millions of people. At present approximately 5.7 million people are affected with the HIV virus. This estimate is projected to increase in the next few years. India is home for 10% of all HIV infected persons in the world and 60% of the Asian HIV infected population. India has the largest number of HIV infected individuals in year 2006 in the whole world. The pandemic is essentially out of control with HIV infection crossing over from high-risk groups to the general population now. An urgent need exists to improve infrastructure and personnel to provide adequate screening, prevention and therapeutic services for this huge number of HIV infected individuals. In view of rapid spread of HIV infection, there is a compelling need for appropriate treatment of HIV infected individuals to decrease mortality. HAART is well known to decrease mortality due to HIV infection. However, access to HAART is poor in several areas in India. Lack of infrastructure, lack of political will, costs of HAART and lack of funding are some main reasons for poor access to HAART. Based on a study published in Journal of American Medical Association by Attaran et al. (10) lack of funding was found to be most serious problem as opposed to popular belief that patent regulations prohibit access to drugs in developing countries.

RATIONALE FOR THE RECOMMENDATION

‘Increase in International Aid to India to improve structure and function of regional health care system to enable screening, diagnosis of HIV infection and administration of HAART therapy

The recommendation meets the criteria of effectiveness: The new policy recommendation will certainly provide the Indian health care system the financial resources to improve the structure and delivery of health care including access to

HAART medications. As a result of better delivery of health care, one would probably fore see a decrease in mortality and morbidity due to HIV related infection as well as improvement in CD4 T cell counts and Viral load measurement among those being treated with HAART. International aid from developed nations should be allocated to the governmental agencies under the agreement that they will monitor compliance with TRIPS. By holding the governmental agencies responsible to act as the monitor for Indian pharmaceutical companies regarding compliance with TRIPS, one can expect more success in enforcing the regulations. This would certainly be at the interest of the pharmaceutical industry that provides the R & D related expenses for manufacture of high cost HAART. Improved regulated use of HAART is a powerful stimulus for market competition between pharmaceuticals that will help lower costs of medications.

The recommendation meets the criteria of efficiency: Increasing International aid to India to fund HIV disease control and therapy will certainly benefit health care costs of HIV infected patients. The local governments will certainly have more financial resources to provide the much needed health care for such patients. The pharmaceutical industry will benefit indirectly from this, as improved health care delivery will lead to higher demand for HAART that in turn must be available at reasonable prices regulated by TRIPS. The stakeholders who may not benefit from this recommendation are the Indian Pharmaceutical industry that will be prevented from manufacturing low cost generic medications under TRIPS.

An initial increase in health care treatment costs due to use of health care by more numbers of HIV infected individuals will be balanced indirectly by subsequent improvement in their overall health status due to availability of HAART. The International funding will also directly aid initial costs of improving health care delivery and access to HAART. More need for HAART will drive up healthy competition among pharmaceuticals and lead to drug price control through a market driven approach.

The recommendation meets the criteria of equity with respect to patients as well as nations: More HIV infected individuals will have access to HAART therapy if health care delivery improves. HAART becomes affordable to an increasing number of HIV infected patients. However, the developed nations are faced with bearing the costs of health care of HIV infected patients in developing poor countries. Although this raises the ethical issue of who pays for the

HIV treatment in India, there are few in the world that believe against assisting people in need. Having said that the world has a moral obligation to provide equal right towards health for all, individual nations may still not perceive this an obligation and hence may abstain from participating in the aid.

The recommendation certainly improves adherence to legal standards: The rights of all stakeholders in this situation will be respected. There will be less international repercussions as a result of TRIPS regulations if poor nations are able to buy HAART using financial aid. More cooperation and compliance from TRIPS participants will lead to uniform distribution of HAART and improved competition among pharmaceuticals that will drive HAART prices down.

The recommendation is politically acceptable to the recipient country but may not be the case with the donor nations: Financial aid will certainly be welcome by the local governments for HIV disease control, not to mention the relief of the HIV infected patients in India. However, donor countries may have opposition for allocation of funds towards humanitarian relief especially when such nations have their domestic issues and policies that require more financial resource allocation. Certainly, the political and market system in India will be able to accept financial aid towards improving HIV disease control. India now has a national organization for control of AIDS that can be charged with the responsibility of improving health care delivery.

The recommendation may be subject to administrative hurdles and may not improve over time: Administrative hurdles may prevent delivery of health care to HIV infected patients. Problems with handling the allocated funds at all levels of the government may reduce the impact of this reform at the grass root level. International aid is subject to change over time and provides limited scope for an increase that is required to handle any rise in initial costs of improved health care delivery. Whether this recommendation will survive the test of time remains to be seen. Certainly, there are examples of recent increases in US bank and WHO funding for HIV disease control in India. In view of the alarming rise in HIV infection, more funding is needed at present to improve the infrastructure required for delivery of health care to an increasing number of HIV patients as well control and prevent further spread of HIV infection.

CONCLUSION

In light of an ever increasing threat of the uncontrolled

spread of HIV infection to pandemic proportions in populous developing countries like India, International cooperation and aid is extremely important to tackle this enormous disease burden and improve access to health care for millions of HIV infected patients in the Indian subcontinent. The urgent need for international aid to improve access to HAART is best articulated by Attaran et al (10) who conclude from their study on access to HIV drugs in Africa as quoted below, "a variety of de facto barriers are more responsible for impeding access to antiretroviral treatment, including but not limited to the poverty, the high cost of antiretroviral treatment, national regulatory requirements for medicines, tariffs and sales taxes, and, above all, a lack of sufficient international financial aid to fund antiretroviral treatment. We consider these findings in light of policies for enhancing antiretroviral treatment access in poor countries". Improving health care of HIV infected individuals will increase the demand for therapeutic HIV drugs that in turn can stimulate the international market to competitively drive down cost of these medications especially if local governments can buy drugs in bulk from pharmaceutical companies. (11)

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