

# Research Report

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## Special Conference I – Innovative Solutions

### Developing Policies to Improve the Availability of Generic Medicines in LEDC's Combating HIV/Aids

MUNISH '11



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<b>Forum:</b>	Special Conference 1 – Innovative Solutions
<b>Issue:</b>	Developing policies to improve the availability of generic medicines in LEDC's combating HIV/Aids
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## Introduction

The issue of HIV/AIDS treatment in less economically developed countries has been one that has gathered a lot of attention from international groups in recent times as a result of the huge increase in the number of HIV/AIDS cases after 1985. Initially, countries around the globe were concerned about treatment of the drug, but as time passed, it became apparent that the ones who were most affected by the pandemic were those who were not in the right financial situation to be able to fund their treatment, namely in LEDCs. This is because in LEDCs the average income is low which makes it harder on individual and families living with HIV/AIDS infected members, and secondly because in LEDCs the government is unable to subsidize the industry for HIV/AIDS treatment well enough to control the problem. Some would argue this is because the prices of HIV/AIDS medications which can reach up to US\$2300 per month for just one individual. Now, one may be able to see why **generic drugs** are useful especially in these areas, as they would greatly aid both the country and sufferers in the treatment of HIV/AIDS. Generic drugs are made when the patent for a drug is no longer valid; this makes the cost of production (and consequently the price of the drug) less than the branded equivalent because the generic manufacturer does not employ capital resources in the development and testing of the drug.

## Definition of Key Terms

**HIV/AIDS:** Human Immunodeficiency Virus – Acquired Immune Deficiency Syndrome. It is a disease which progressively attacks and deteriorates the human immune system making individuals much more vulnerable to the effects of pathogens. As of now, it cannot be cured but there are a host of drugs available that are used to

**Generic Drug:** “A drug product that is comparable to brand/reference listed drug product in dosage form, strength, route of administration, quality and performance characteristics, and intended use.” In essence a generic drug is a drug that bears no branding and is not necessarily manufactured by a large pharmaceutical company, but still can match the effectiveness of branded drugs.

**Antiretroviral Drugs:** “Medication for the treatment of infection by retroviruses such as the human immunodeficiency virus.”

**HAART:** or **Highly Active Antiretroviral Therapy:** The medical approach to curing HIV that involves a combinations of antiretroviral drugs. HAART is fairly effective in treating cases, however, due to the fact that there is a combination of drugs being taken, this compounds the cost of treatment making it doubly harder for people in LEDCs to receive this form of treatment.



## General Overview

The distribution of generic drugs to treat HIV/AIDS has been hindered by the presence and influence of big pharmaceutical corporations in LEDCs and the power that they wield over governments in afflicted areas. For example let's assume the Boehringer Ingelheim pharmaceutical company that manufactures the costly Atrivus pills, which are used to treat sufferers of HIV in **HAART**, encounters a manufacturer who can legally manufacture a generic version of Atrivus at a significantly lower price. Boehringer Ingelheim will do all it can to prevent the distribution of the generic drug as they would lose profits when sufferers begin buying the more economical generic drugs.

Large pharmaceutical companies often pressure governments in LEDCs to prohibit the sale and distribution of generic drugs as a result. A good example of this is the Kenyan government introducing an anti-generic drug law in 2009 in order to maintain the profits of pharmaceutical companies. The Indian government criticised this move and suggested that the same might be occurring in other parts of Africa such as Uganda and Zambia where AIDS prevalence rates are at 6.5% and 13.5% respectively.

Worryingly, the AIDS prevalence rates are still at a fairly high 6.3% in Kenya, and it is estimated that 50% of the Kenyan population is below the poverty line. This could lead to a very high spike in AIDS-related deaths in Kenya over the next few years, which may spill into Uganda and Zambia, should similar legislation come into place there.

However, even as Indian authorities advised against the criminalization of selling generic drugs in Kenya, their own government has forced itself into a quandary, which might affect HIV/AIDS patients all over the globe. Roughly half the world's generic AIDS medicines and more than three quarters of all AIDS drugs administered by medical practitioners are manufactured in India, as there are very loose restrictions on counterfeiting and the production of generic drugs. This is set to change as India enters into a free trade agreement with the European Union, which stipulates that India must conform to intellectual property regulations practiced in the EU, which would curtail the legal status of the production of generic drugs in India. This may have catastrophic effects on the fight against HIV/AIDS all over the world, let alone LEDCs as it now means that up to 80% of all drugs used in medical facilities would not be available soon after the agreement is finalised.

## Major Parties Involved

The ICRC or the International Committee of the Red Cross would be the most obvious candidate to be the most involved member party involved, and has been distributing HIV/AIDS medicines on the field. The ICRC policy states that it will "undertake operational measures aimed at ensuring continuous progress in the availability of treatment and care for people living with HIV/AIDS"

Also, since roughly a fifth of all reported HIV/AIDS cases are from Sub Saharan Africa, and Africa as a whole, countries such as Swaziland, Botswana, Lesotho, South Africa, Zimbabwe and Zambia should be a key part of this debate in order to gather capital resources and financial aid from more economically developed member states to help



address this issue. East, South and South-East Asia also constitute 16% of worldwide HIV/AIDS and thus, members such as but not limited to India, Pakistan, Bangladesh and Indonesia must also be involved in the debate. India is very pro-generic drugs and has urged the leaders of the African continent to follow in their footsteps, however they are also in the process of negotiating a free trade agreement with the European Union which may hinder progress in this field by introducing European intellectual property regulations into the largest generic medicine producer in the world. The more dominant member parties of the European Union and the Indian delegation should be active in this debate to circumvent such an occurrence.

## Timeline of Key Events

1984: Western Scientists become aware that AIDS is widespread in Africa

1987: AZT is the first drug approved for treating AIDS

1993: AZT is shown to be of no benefit to those in the early stages of HIV infection.

1996: Combination antiretroviral treatment is shown to be highly effective against HIV, with many infected people in MEDCs

2007: Several batches of generic drugs are brought into Brazil by Indian firm Ranbaxy, after the President decrees that Efavirenz be licensed to all.

2009: Kenya approves an anti-generic drug law, which restricts the importing of generic drugs from that are counterfeits of drugs patented elsewhere.

## Previous Attempts to Resolve the Issue

In 2007, President of the Federal Republic of Brazil, Luiz Inácio Lula da Silva announced that he would be implementing legislation that would require the manufacturers of a drug named Efavirenz (sold under the brand names of Sustiva and Stocrin) to license the drug to other firms. Once this legislation was in place, 8 batches of generic Efavirenz manufactured by Indian pharmaceutical firm Ranbaxy arrived in Brazil. Merck Sharp & Dohme, the firm that holds the patent for the drug was paid 1.5% of the transaction in royalties by the government. This was a very good example for how governments should increase the availability of generic drugs in their country.

## Possible Solutions

Firstly, I suggest that all member parties represented in the committee work towards a consensus in which all member parties comply with the requests of humanitarian organisations in the provision of generic drugs. This may include introducing new universal legislation to be implemented in all member states which requires governments to remove restrictions on the production of generic drugs in the form of loosening intellectual property rights laws in order to accommodate the demand and supply of generic drugs. This may seem tough for large-scale pharmaceutical companies in this challenging economic weather, but we must remember that lives are at stake, and that the priority is delivering the necessary medication to wherever it is most needed.



Similarly, we can call for the licensing of branded drugs to generic medication manufacturers in an agreement where the patent holders of the drug receive their respective royalty payment, as done in Brazil in 2007. However, Brazil is an industrializing nation with sufficient capital to employ such a tactic. Thus for LEDCs to be able to do the same, they would require sufficient capital from their more economically developed counterparts to pay such royalties.

The ICRC states in its Field Guide that it assesses the conflict environment and subsequently the humanitarian climate of an afflicted area before it can assess the HIV/AIDS situation. Thus, in order to increase the availability of HIV treatment, generic and branded, one would have to encourage the governments of war-torn HIV-infected areas to suspend military activities and/or declare a ceasefire with in conjunction with another committee in order to help facilitate the actions taken by organisations aiming to relieve an area of its HIV/AIDS issues. Since this will lead to an increase in the supply of AIDS medicines in affected areas, naturally it would also mean an increase in the number of generic drugs being supplied in that area.

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