

TAC Fact Sheet

Brazil's HIV/AIDS Treatment Programme

Why a Fact Sheet on Brazil?

Many South Africans know Brazil for its brilliant soccer players, such as Pele, Romario and Ronaldo. Like South Africa it is a beautiful country, containing magnificent coastlines, the world's largest and most diverse rainforests and the spectacular city, Rio de Janeiro. Unfortunately, like South Africa, the major cities are plagued by poverty.

There is an important reason why HIV/AIDS activists should know about Brazil. It has implemented a treatment programme which dispenses HIV/AIDS medicines to over 90,000 people. According to Medecins Sans Frontieres (MSF), the number of AIDS deaths have decreased by half since the programme was introduced. UNAIDS has cited Brazil as a *best practice*. Recently, the Brazilian government offered to transfer knowledge and medicines to other countries with HIV/AIDS epidemics.

This fact sheet describes what Brazil has achieved, the treatment programme's strengths and weaknesses, as well as issues relevant to South Africa.

Some Facts About Brazil

Brazil is the world's 5th largest country in both area and population, with over 165 million people. It has a similar per capita GDP to South Africa and a highly unequal income distribution, with many people living in poverty. The capital is Brasilia, but the biggest cities are Sao Paulo and Rio de Janeiro.

UNAIDS estimates that 540,000 Brazilians have HIV/AIDS. As in South Africa, the highest prevalence of the disease is among poor people. The disease is growing among women, though twice as many men are currently infected

Anti-retroviral (ARV) Therapy and HIV/AIDS

In the United States and Europe, AIDS deaths have decreased substantially over the last few years. People with HIV/AIDS in rich countries are living longer, healthier lives. This has occurred due to new medicines being developed for treating the disease. There are two categories

of medicines, those that treat opportunistic infections and those that fight HIV itself, known as anti-retroviral drugs.

Access to ARV Drugs in Poor Countries

Anti-retroviral drugs are expensive. Few poor countries have managed to make access to these drugs available to most of their citizens. Brazil, Uruguay, Costa Rica and to a lesser extent, Thailand, Panamá, Argentina and Chile are exceptions. One of the reasons why these drugs are expensive is that in most countries, multinational pharmaceutical companies hold *patents* on them.

Generic medicines are usually much cheaper than patented drugs. Activists have been arguing that *brand-name* drug manufacturers such as Bristol-Myers Squibb and GlaxoSmithKline have been abusing their patents and making excessive profits. HIV/AIDS requires patents to be overridden for the public good. Therefore it is necessary for generic anti-retroviral and opportunistic infection medicines to be manufactured to reduce the cost of HIV/AIDS treatment. This will allow governments in poor countries to treat HIV/AIDS on a large scale and provide medicines for free to people who cannot afford them.

What has Brazil Done?

Brazil has implemented a policy of providing anti-retroviral treatment to people with HIV/AIDS. This has been achieved through the manufacture of generic medicines (not only anti-retrovirals) with substantial government investment. According to MSF and the Brazilian government, this has had the following tangible results

- The price of anti-retroviral medication has dropped by 72.5%, on average, since 1996 (In contrast, the prices of imported drugs declined by an average of 9.6%.)
- Over 85,000 people have been put onto the treatment programme
- HIV/AIDS deaths have been reduced by approximately 50% since the policy was implemented.
- The quality of life of people with HIV/AIDS has improved significantly.



Johannesburg: Tel: 011-403 0265 Facsimile: 011-403 2106
Cape Town: Tel: 021-364 5489 Facsimile: 021-361 7501
Email: info@tac.org.za Website: www.tac.org.za

There are treatments which allow people with HIV/AIDS to live much longer, healthier lives. Campaign for safe, affordable generic drugs.

Brazil's HIV/AIDS Treatment Programme

How Does the Brazilian System Work?

The government has set up a pharmaceutical company called FarManguinhos which conducts research into producing the raw materials of medical drugs. It transfers this information to other companies which then produce the raw materials. FarManguinhos negotiates the price of the raw materials which it purchases back from the producers. It then produces the final products from the raw materials.

Brazil is divided into states. Some of these states have set up public pharmaceutical producers as well. In addition to the public companies, there are private ones which research, develop and produce generic medicines. These companies purchase some raw materials internationally from India, Japan, Korea and China.

The Ministry of Health purchases about 40% of its medicines from FarManguinhos. The remainder is purchased through open international tenders. Private and state-run Brazilian companies as well as multinational pharmaceutical companies compete for these tenders.

Activists often ask pharmaceutical companies to explain how they calculate the prices of their medicines. They almost always refuse. In Brazil, however, companies are legally obliged to explain how their drug prices are calculated! FarManguinhos is responsible for calculating the price of medicines for the Ministry of Health. These prices usually include a 10% mark-up, which FarManguinhos uses to re-invest into the company. All other companies have to make their HIV/AIDS drugs the same price as FarManguinhos when they sell them to the Ministry of Health.

Other Aspects of the Brazilian Programme

Manufacturing drugs is not enough for a successful treatment programme. Brazil has implemented the following activities

- Policy of universal access to HIV/AIDS treatment and anti-retroviral treatment, in particular
- Extensive STD and AIDS prevention and care facilities
- Prevention of mother-to-child HIV/AIDS transmission
- National laboratory network for conducting CD4 and viral load counts
- National system for ensuring the quality of the laboratory testing facilities
- Extensive care facilities and procedures
- Monitoring of patient take-up rates of HIV/AIDS treatments
- National computerised system for drugs control, which monitors dispensing and automatically detects and corrects incorrect prescriptions
- National computerised system for monitoring laboratory tests

South Africa can also learn from Brazil's prevention programme which includes advertisements for mother-to-child transmission prevention. Unlike the South African *Abstain, Be faithful or Condomise* (ABC) campaign, there is an unambiguous commitment to condoms as a means of preventing HIV transmission. Perhaps this is one of the

reasons why the infection rate is so much lower than South Africa's. This is despite Brazil having a strong Roman Catholic church and where 73% of the population is Catholic.

Care Facilities and Procedures

Brazil has an extensive care network outside of conventional hospitals. 145 specialised care centres comprise a team consisting of a doctor, dentist, nurse, psychologist and social worker who provide support and care to patients and their families. 66 day hospitals provide medication, diagnostics and minor surgery to patients who do not require hospital admission. 50 home therapeutic care units provide an alternative to patients needing to be hospitalised. These involve the family in treatment and reduce the pressure on hospitals. According to the Institute of Economic Research Foundation at Sao Paulo University, this system has reduced costs and improved patient outcomes.



Land of Great Soccer Players and ...



... Universal Access to HIV/AIDS Treatment!

Legal Issues

Members of the World Trade Organisation (WTO), such as South Africa and Brazil are bound to an agreement called the *Trade Related Aspects of Intellectual Property Rights* (TRIPS) agreement. TRIPS governs how countries implement patent laws. Although many anti-WTO demonstrators have rallied against TRIPS because it strengthens patents, the agreement does not have to be changed to accommodate the HIV/AIDS crisis. This is because it contains exemptions for health, nutrition and security. These exemptions allow a government to introduce two measures when it wishes to override a patent, *compulsory licenses* and *parallel imports* (see glossary).

Brazil did not grant pharmaceutical patents prior to 1995, when it joined the WTO. The WTO TRIPS agreement gives Brazil until 2005 to modify its intellectual property legislation to change this. However, as a result of

Brazil's HIV/AIDS Treatment Programme

international pressure, Brazil passed a law to allow pharmaceutical patent protection which came into effect in 1997. According to MSF, the law offers stronger patent protection than required by TRIPS, but still allows Brazil to issue compulsory licenses.

As a result of Brazil's late entry to TRIPS, it has never needed to implement a compulsory license for the generics it has manufactured. However, new anti-retroviral drugs such as ritonavir, nelfinavir and efavirenz have been patented. For the first time, it might be necessary for the Brazilian government to order compulsory licenses, and it has stated its intention to do so. The pharmaceutical industry, the US and EU governments have applied extensive pressure against countries which have pursued compulsory licenses.

Reasons for Success

According to the Brazilian Ministry of Health, there are a number of reasons for its mostly successful fight against the HIV/AIDS epidemic.

- Brazil responded early to the epidemic. It has taken positive action against HIV/AIDS since the mid-1980s.
- There has been substantial co-operation, though not without conflict, between the Brazilian government and civil society. Civil society has played an essential role in prevention programmes and treatment access initiatives.
- There has been substantial co-operation between Brazilian and international institutions. This has taken place at many levels with many countries, both rich and poor, resulting in the development of skills and knowledge among health-care personnel and civil society organisations.
- A World Bank loan of US\$325 million has been successfully used to finance HIV/AIDS and Sexually Transmitted Disease (STD) activities.
- The Brazilian government and civil society have ignored the prevailing, and we believe wrong, views on how a poor country should manage the HIV/AIDS epidemic.
- The Brazilian government policy has been to offer universal access to HIV/AIDS treatment, thereby ensuring that poor people and women with HIV have, to a large extent, not been excluded from the benefits of the HIV/AIDS programme.

Issues

The Brazilian programme has not been without problems. It is important for activists to be aware of these issues so that they (1) can campaign for them to be remedied, (2) try to prevent these problems from occurring in other countries and (3) know how to respond to critics of the Brazilian programme from both AIDS denialists and the pharmaceutical industry. Some of the issues that Brazil has faced are discussed below. Also discussed are additional issues that countries like South Africa will need to be aware of.

Safety

Anti-retroviral drugs are effective, but they are also dangerous, especially if not used properly or if they are poorly manufactured. Before a new drug is made available to the public, it should be tested extensively and pass a *bio-equivalence* test (see glossary).

Many of the Brazilian anti-retroviral drugs are only expected to have their bio-equivalence tests completed early in 2001. However, they have been distributed to the Brazilian public for the last few years. Strictly speaking, this is a breach of safety protocol and Brazilian activists have criticised the Brazilian government and pharmaceutical companies for taking too long to complete these tests.

In dealing with the HIV/AIDS epidemic, there is a tension between giving people essential medicines as soon as they become available or waiting until those medicines have been proven safe and effective. Brazil, by distributing generic medicines before their bio-equivalence has been proven, have taken a calculated risk which seems to have paid off on the basis that AIDS deaths have been reduced by 50%. Nevertheless, MSF correctly states that "countries are recommended to wait until the [bio]-equivalence studies are completed before importing, given the sensitivity regarding these products."

MSF has assessed FarManguinhos's site and found that it meets international quality standards.

World Bank Loan

Many Brazilian HIV/AIDS activities have been funded through a World Bank loan. This loan expires in 2002. Activists are concerned about where the funds for continuing the programme will come from after that date. Organisations like Jubilee 2000 are campaigning for debt relief to poor countries which will free up funds for spending on social welfare.

AIDS Mortality Rate Still too High

The reduction of AIDS deaths in Brazil by 50% is a remarkable achievement, but the United States, Canada and European countries have achieved higher rates. Of course, these are much richer countries with far greater resources, but poor countries must aim for the same success rates as rich ones. Activists should not be satisfied until this has been achieved.

Economies of Scale and Mass Production

The Brazilian offer of knowledge transfer and generic medicines to poor countries is an act of international solidarity. It is in South Africa's and Brazil's interests for a mutually beneficial agreement to be reached. FarManguinhos is currently operating at 50% capacity. By increasing production the per-unit costs of manufacturing medicines will be reduced, thereby lowering the price of these medicines. However, Brazil's current production capabilities will not meet all of the needs of South Africa's large HIV-positive population. Therefore, South Africa needs to investigate producing generic medicines, particularly medicines which Brazil does not produce enough of. Doing this will (1) create a beneficial, interdependent relationship between the two countries and (2) help develop a sustainable third-world pharmaceutical industry which will be able to better meet the treatment

Brazil's HIV/AIDS Treatment Programme

needs of poor countries by putting more research and development into diseases like Tuberculosis and Malaria, something that is unlikely to happen while the pharmaceutical industry is dominated by multinationals based in rich countries.

Information Systems and Reinventing the Wheel

Brazil has implemented sophisticated information systems for dealing with the epidemic (e.g. drug prescription control and laboratory system control). South African government and civil society should resist the temptation to reinvent the wheel by hiring consultants at astronomical expense to implement new systems to achieve the same objectives. Instead the government should consider purchasing and implementing the Brazilian systems, if they are deemed suitable.

Conclusions

By combining treatment and prevention messages within a human rights context, the HIV/AIDS epidemic is, for now anyway, being brought under control in Brazil. It has shown that universal access to HIV/AIDS treatment in poor countries is possible. An important part of the solution involves developing a sustainable generic pharmaceutical industry. This will be better for South Africa than the *differential pricing* schemes being offered by the large multinational pharmaceutical companies. Although these schemes will improve access to treatment, they are unlikely to be sustainable, since they hold little incentive for the multinationals.

South Africa has many more people with HIV/AIDS than Brazil and will require much larger quantities of medicines and more care facilities. South Africa has also made a late start to combating the HIV/AIDS epidemic. Nevertheless, it has a large and, in many places, sophisticated health-care infrastructure, as well as some of the technological knowledge and infrastructure for developing a generic pharmaceutical industry. Opposition party leader Tony Leon, whose party has pandered to the multinational pharmaceutical industry and come out against generic substitution, has stated that universal access to anti-retroviral treatment is unaffordable in South Africa. Brazil has shown that Leon can be proven wrong. To do so will require government and civil society determination and co-operation.

References

Report on Brazil available from MSF.

Brazil: What Went Right? The Global Challenge of Access to Treatment & the Issue of Compulsory Licensing. Mark Harrington, Treatment Action Group, Brazil, 2000 (available at www.aidsinfonyc.org/tag/activism/brazil.html).

The Brazilian STD and AIDS Programme. Published by the Brazilian STD and AIDS Programme, Brazil, 2000.

The Brazilian Response to HIV/AIDS. Brazilian Ministry of Health, Secretariat for Health Policies and the National Co-ordination for STD and AIDS, Brazil, 2000.

Thank you to Jorge Belouqui for his advice.

Glossary

Bio-equivalence Test This is a scientific test which determines if a drug has the same active ingredients and behaves the same way in a human body as the brand-name drug. If it does, then the drug is a generic.

Brand-name Drug This is the drug manufactured by the patent holder.

Compulsory License This is an order by the state to a public or private organisation to produce or import a product which is under patent. The patent holder has to be paid a small compensation.

Differential Pricing Scheme This is where pharmaceutical companies charge much lower prices in poor countries than rich countries for their patented drugs. There have been suggestions that the pharmaceutical companies will do this as a result of activist pressure.

Generic drug is a medicine that is almost identical to a patented drug, but manufactured by a different company.

Parallel Import This occurs when a country imports a patented product at a cheaper price from another country. Compulsory licensing of medicines necessarily involves the production of generics. A parallel import, however, is not a generic.

Patent If a company own a patent on a product, it means that only that company may produce or sell that product.

Per Capita GDP This is the amount of money produced by a country divided by the number of people.

The following table is a selection of generic anti-retrovirals produced in Brazil and, except for the South African prices, has been constructed using data from MSF. Prices are per unit in US Dollars. Rand/Dollar Exchange Rate = 7.3

	1996 Price	2000 Price	2001 Price	Best 2000 SA Price
AZT (100mg)	0.5	0.18	0.15	0.32
AZT (300mg) + 3TC (150mg)	3.3	0.72	0.68	2.74
ddI (100mg)	1.8	0.51	0.49	1.00
ddC (0.75mg)	1.5	0.08	Unknown	Unknown
3TC (150mg)	2.8	0.83	0.35	3.12
d4T (40mg)	2.2	0.28	0.27	3.51
indinavir (400mg)	N/A	1.72	1.6	1.67
nevirapine (200mg)	N/A	2.68	1.25	4.35