

Universal access to AIDS medicines: the Brazilian experience¹

Paulo Roberto Teixeira²

¹ Article based on an interview by the author with Cristina Câmara, special advisor in charge of the Civil Society Liaison and Human Rights Unit, and Flávio Guilherme de Souza Pontes, advisor to the Communications Division, both of the Brazilian National Commission on STD/AIDS

² Coordinator of the Brazilian National STD/AIDS Program
E-mail: pteixeira@aids.gov.br

INTRODUCTION

This article focuses on the Brazilian policy for distribution of medicines to persons living with HIV/AIDS. It attempts to present readers with the social scenario in which this policy has been developed and implemented, and describes the history of how the epidemic has been dealt with in Brazil.

Some historical references are mentioned in order to provide a better understanding of the principles underlying the Brazilian policy, which primarily result from the inevitable association between public health and human rights in the AIDS pandemic. Among such references are the Brazilian public health movement, the creation of the Unified National Health System (SUS) under the country's 1988 Constitution, and links between the government and civil society organizations (CSO) in Brazil.

An analysis of the international scenario provides an idea of the role

and repercussions of the Brazilian STD/AIDS Program. The article describes the sequence of events beginning with the 13th International AIDS Conference in 2000 in Durban, South Africa, through the approval by the World Trade Organization (WTO) of a separate Ministerial Declaration on the TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights) and Public Health in order to help readers grasp the importance of social and political mobilization in this process, culminating with the victory by developing countries at the 4th WTO Ministerial Conference in Doha, Qatar, in relation to increased flexibility in the TRIPS agreement.

UNIVERSAL ACCESS TO AIDS MEDICINES: THE BRAZILIAN EXPERIENCE

Before focusing on the core issue, I believe that some references will help situate readers. I began my public service career in the Public

Dermatology Division of the São Paulo State Health Department. At the time there were two lines of work in the institution: the first priority was Hansen's disease, and the second was sexually transmissible diseases (STD). Having worked in the field of STD in the State of São Paulo since 1978, I was designated to organize the first program to respond to AIDS in Brazil. At the time there was already a strong public health movement in both São Paulo and Brazil as a whole from the political and philosophical point of view, as a class organization issue for health professionals. The movement, consisting of public health professionals, developed a critique of the health policy practiced by the military government and conducted discussions that led to the creation of the Unified National Health System (SUS) and the approval of Constitutional provisions to guarantee universal social protection, unification of pub-

lic health services, and participation by civil society.

The public health movement was present in 1983 when the AIDS program was organized in São Paulo, and under the first democratic Administration elected in the State, Governor Franco Montoro and the State Health Secretary responded quickly and effectively to demands by the community. This is an important reference for understanding why there was such an early and (for the time) such a broad response to AIDS. From the beginning, the São Paulo AIDS Program was organized with all the components still existent today, including prevention, epidemiological surveillance, treatment, and human rights, in addition to a strong component of linkage with CSO, which at the time focused primarily on the rights of homosexuals.

The São Paulo Program soon spilled over to other States of Brazil. The largest States began setting up their own programs to fight HIV as soon as they detected their first cases. Meanwhile, the National Program in the Ministry of Health took four years to effectively get off the ground. The first initiatives at the national level began in the second half of 1985, when there were already programs organized in 13 States. For all practical purposes the National STD/AIDS Program was not organized in the Ministry of Health until 1986. Thus, even at the governmental level, the Brazilian re-

sponse to the AIDS epidemic emerged from the bottom up and in a decentralized way, although social-political dynamics generated fluctuations in this trend over time.

Another important reference for the creation and success of the Brazilian STD/AIDS Program was the fact that the Dermatology Division of the São Paulo State Health Department already included a strong community mobilization component and the struggle for the rights of people with Hansen's disease and against the stigma and discrimination associated with it. In terms of discrimination and stigma, one can easily draw parallels between Hansen's disease and AIDS. Therefore it was significant that the State Dermatology Division already had a multidisciplinary team emphasizing community involvement and the struggle for the rights of affected individuals. The longstanding experience with Hansen's disease both supported and provided the initial structure needed to set up the AIDS Program. At the time there was a strong link between AIDS and homosexuality, which also proved problematic. If there had not been a team in place to deal with issues pertaining to rights, stigma, and minorities as a government commitment and responsibility, it might have been much more difficult to create an AIDS Program with the above-mentioned characteristics. Taking on work with AIDS required a team-level discussion and resulted

in an absolutely conscientious decision to tackle the problem. At that stage the staff professionals were not required to work specifically with AIDS, because there were alternatives. Several public universities proposed to become reference centers on behalf of the State Health Department.

In relation to medicines for AIDS, in 1989 the State of São Paulo began purchasing and distributing AZT, the first anti-retroviral drug distributed by the public health care system in Brazil. The first purchase covered only a small portion of the demand in the State: no more than 7% of the patients that needed the drug. However, although this initial supply was limited, it was a deliberate initiative as part of a strategy to create a need, to generate demands, and to spark involvement by society on the issue of anti-retroviral treatment in Brazil. The first free distribution was in the city of São Paulo, followed shortly by Santos (in the same State), which also began purchasing AZT. The Mayor of Santos at the time was from the Workers' Party (PT).

These initiatives helped mobilize public opinion and the community, and in 1990 the Ministry of Health decided to begin purchasing all the AIDS drugs available on the market, including anti-retroviral drugs and medicines for opportunistic diseases. In São Paulo, where AZT was already partially available, the decision by the Ministry of Health allowed for universal distribution. What does

universal distribution mean? Any citizen, even individuals in treatment covered by private health plans or health care outsourced by the government, had the right to receive publicly distributed AIDS medicines. This policy contradicted the Ministry of Health guidelines, according to which the medicines were only supposed to be distributed to individuals enrolled in public treatment centers. In other areas of the country, adoption of the Ministry of Health guidelines resulted in undesirable practices like resale of medicines by patients themselves. As mentioned, there were institutions that required patients to be enrolled in specified public health care services, which in turn lacked the capacity to meet the entire demand. Patients needed the medication but could only get appointments six to eight months later. As a result, those 'at the head of the line' and who happened to be poorer began to sell their places in line to others who could pay. It was not until 1993 that a full-scale nation-wide distribution policy was adopted, as already existed in the State of São Paulo.

Before triple therapy was proposed in 1996, AZT, ddC, and ddI were the only drugs available from the anti-retroviral group. Faced with the limited action of these drugs, in reality the greatest concern was over the purchase and regular distribution of medicines for opportunistic diseases,

including acyclovir, pentamidine, amphotericin, and ganciclovir among numerous other drugs.

The adoption of triple therapy led to major changes in the debate on access to AIDS drugs. The efficacy of triple therapy was quickly proven, and the demand increased, sparking greater pressure by the community for access to the publicized benefits. Meanwhile, others were questioning the high cost of treatment for people living with HIV/AIDS. Budget spending on medicines, an issue that was already problematic, took on a larger dimension and the Ministry of Health was somewhat hesitant to maintain the distribution policy, adding new drugs. Thus, the Ministry of Health did not begin distributing 'combo' therapy until 1996-97, whereas São Paulo had already begun in 1995. As a result, the drop in AIDS mortality was first observed in the State of São Paulo, where the first CD4-count network in Brazil had also been set up. Although triple therapy was announced at the 11th International AIDS Conference in 1996 in Vancouver, Canada, since 1995 there was already an absolute consensus that monotherapy should no longer be prescribed, but should be replaced by combination therapy, which required purchasing protease inhibitors.

The Brazilian response to the AIDS epidemic has the following determinants: the demand, broad media cov-

erage, commitment by health professionals, and mobilization by CSO. In general one can say that this struggle has been the result of integrated actions by health professionals and the community within a favorable public opinion scenario. The country is now entering a new era. When the work began in São Paulo, the first social movement was headed by gay rights organizations, but other partners soon emerged, including associations of people with hemophilia and thalassemias. These groups participated because of difficulties in controlling the quality of blood transfusions in the country (70% of hemophiliacs in Brazil were HIV-infected). It was the struggle against the AIDS epidemic that actually led to quality control in the blood supply. After decades of a fruitless struggle against lack of control in Brazil's blood banks, based on AIDS the government gained the legitimacy and a popular mandate for radical intervention. In 1987, in the States of São Paulo and Rio de Janeiro, blood banks frequently had to be inspected with police backup, such was the lack of control and absence of government authority in the blood bank industry.

Everything happened at break-neck speed. The Group to Support AIDS Prevention (GAPA) was set up in São Paulo in 1984 and officially founded in 1985.¹ The basis for this

¹ GAPA was the first CSO created in Brazil in response to the AIDS epidemic.

organization was the community group circulating around the events held by the São Paulo State AIDS Program. In a sense there was a convergence of various existing opportunities, which included issues such as social justice, democracy, human rights, the right to health, community participation, transparency, etc.

Before the advent of triple therapy the reality of people treated in the health services was truly dramatic. There was a terrible lack of beds, outpatient services, professional health care staff, etc. Patients put enormous pressure on health care services, and the scenario was frequently tragic, with clinics and corridors of emergency wards full of patients on gurneys. From 1996 to 1997 there was an increase of some 30% in the number of people with AIDS who turned to health services because of the announcement of free anti-retroviral therapy. However, at the same time it was much less problematic than expected because at the same time these same individuals were no longer occupying the hospital beds and day hospitals, due to the better overall health conditions obtained through the new treatment regimen. If it had not been for combination anti-retroviral therapy, the 30% increase in caseload would have caused a total breakdown in the health care system, beyond any hope of management.

ACTIVISM AND SOCIAL CONTROL

There have been undeniable advances in dealing with the AIDS epidemic, with activism as one of the key determinants. Furthermore, activism will continue to be a determinant in the future response, because the HIV/AIDS epidemic will continue to exist for many decades. Any slip-up may be fatal, from the point of view of both epidemiology and treatment, and to avoid this hazard the role of activists is absolutely crucial, including the maintenance of rigorous epidemiological surveillance, adequate preventive measures, guaranteed access to quality treatment, and human rights, all of which should be part of a continuous process of improvement on the gains already made.

The Brazilian community movement has matured, specialized, and improved. It is now capable of following and participating in all the initiatives and strategies ranging from research work on vaccines to behavioral interventions, a phenomenon that is infrequent in other countries. It obviously has both the political and technical capacity to accompany and invest in the various areas and analyze all the possibilities.

This competence expanded, consolidated, and grew within the overall response to the epidemic. The community movement in Brazil now has huge strategic potential. The movement is focused on anticipat-

ing and analyzing the next 10 to 15 years, while community movements in most developing countries are still struggling for AZT for HIV-positive pregnant women in order to reduce vertical transmission. These characteristics of the Brazilian community movement help lead to increasingly strategic, long-term, sustainable, and well-structured activities.

THE INTERNATIONAL SCENARIO

The milestone that consolidated the Brazilian position in relation to the AIDS epidemic was without a doubt the 13th International AIDS Conference in Durban, South Africa, in July 2000. Since the Brazilian policy of universal access to AIDS drugs was adopted, it has resisted recommendations to the contrary by UN agencies, the World Bank, bilateral cooperative agencies, and other more backward political forces, both domestic and international. Even before triple therapy, Brazil had already achieved extremely important results in the control of tuberculosis and other opportunistic diseases, with a resulting improvement in the quality of life of people living with HIV/AIDS in the country. Such advances have not been experienced by other countries and have gradually become more and more visible in Brazil. This process was consolidated in Durban, where the Brazilian policy received recognition in the international scenario. At the confer-

ence, Brazil presented its policy as an issue of rights for all, all over the world, and demonstrated that other developing countries can also adopt such a policy. Brazil offered its technical support for this purpose, even for local production of AIDS drugs, in a deliberate attitude of entering this international scenario.

Although the results obtained from the policy of universal access to anti-retroviral drugs had already been outlined since the emergence of triple therapy, it was at this time – at the Durban conference – that there was a consolidation and better understanding of the Brazilian policy. This recognition, even on the part of some UN agencies, and the undeniable support of international public opinion were essential for strengthening Brazilian policy and determining the extent of Brazil's participation during the subsequent months in the international scenario.

The 2nd Forum on Horizontal Technical Cooperation in Latin America and the Caribbean, held in Rio de Janeiro in November 2000 and known as Forum 2000, where countries from Latin America and the Caribbean met to outline and discuss common strategies in the struggle against the AIDS epidemic, expanded the international focus on the Brazilian experience and attracted attention from the international media, further bolstering the positive results of the Brazilian experience and the efficacy of the tech-

nology developed by Brazil to deal with the epidemic.

Local production of generics, the possibility of breaking patents, and the offer of technology transfer became instruments for price negotiations with other countries and the pharmaceutical industry, leading to a real reduction in prices on the Brazilian and international markets. Since then the world has identified alternatives to the historical passivity of developing countries in negotiations with the pharmaceutical industry, proving that such negotiations can be conducted favorably, based on political mobilization. There was a turnaround in the discourse on lack of access. Brazil demonstrated low-cost local production, competence in the utilization of complex therapies, and alternative routes to lower-cost access.

Other countries soon discovered that the notion of insurmountable incompetence associated with underdevelopment was outdated. They began to trust in their own capabilities, in their own strength. This was a most important change.

There is no basis to the warning by some laboratories that the Brazilian position could lead to a reduction in investments for research and development of new drugs. The pharmaceutical industry will continue to be highly lucrative. What should happen is the necessary adjustment of profit margins, especially in the case of poor and developing countries. Profits may even increase,

because the market will expand. Considering that the industries' substantial profit occurs in the primary market, that is, where this discussion is not taking place, it makes no sense that profits would be reduced or that there would be no new investments. At any rate, this debate should serve as a warning for governments and society to begin to think of alternative forms of public investment in drug research and development, currently in the hands of private enterprise.

The Brazilian experience has shown tremendous influence in the recent international scenario marked by the United Nations General Assembly Special Session on HIV/AIDS (UNGASS), the WTO Ministerial Declaration on the TRIPS Agreement and Public Health, and the debate on drug patents. The results obtained in Brazil, particularly with anti-retroviral therapy, had a direct impact on the global discussion and behavior.

In late 2001, WTO member countries meeting in Qatar passed a declaration proposed by Brazil and India stating that the TRIPS agreement could not override issues of public health. The declaration considered the right to health as a fundamental reference for interpreting TRIPS, thus avoiding possible retaliations against measures taken by individual countries to protect their public health. According to the declaration approved by the 142 participating countries, it was up to each

country to set rules for granting compulsory licensing and, whenever necessary, criteria for characterizing a national public health emergency.

Yet this was not the only victory. Over the course of 2001, countries led by Brazil which had essentially been defending public health issues had succeeded in including and approving, by the UN Human Rights Commission, the definition of access to medicines as a human rights issue. The resolution was passed in April 2001 with 52 votes in favor and only one abstention, the United States. Less than a month after the victory in the Commission, the World Health Organization (WHO) unanimously passed another similar resolution, submitted by the Brazilian government, guaranteeing access to AIDS medicines as a fundamental human right.

Although the United States had taken a stance against increasing the flexibility of the TRIPS agreement at the time, the U.S. government announced during the UNGASS that it was withdrawing the complaint it had filed in the WTO against the Brazilian intellectual property law. The request to convene a “panel” in which the Brazilian law was supposed to be challenged had been filed in February 2001.

However, negotiations were just beginning to include a separate declaration on TRIPS and public health on the agenda of the 4th WTO Ministerial Conference, held in November

2001 in Qatar. In September of that same year, under Brazilian pressure, a preparatory meeting for the Ministerial Conference agreed to include the theme. However, the following month, during another preparatory meeting, negotiations over a consensus text for a separate declaration reached an impasse and were suspended; the final decision on whether to include a declaration was postponed for Qatar and thus depended on direct negotiations between Ministers of State at that meeting.

The national and international media played a key role in this process, not only providing space to increase the transparency of negotiations over the inclusion or exclusion of the separate declaration, but also issuing important opinions about increased flexibility of the TRIPS agreement. For example, two weeks before the 4th WTO Ministerial Conference a *New York Times* editorial expressed support for the proposal by Brazil and other developing countries in favor of signing a separate ministerial declaration on TRIPS and public health.

However, the proposed declaration still underwent intense negotiations during the WTO Ministerial Conference in Qatar, and although it was not passed with the precise wording proposed by Brazil and other developing countries, the final text guaranteed that the TRIPS agreement could not prevent member countries from taking measures to

protect their public health and that it should be interpreted and implemented in keeping with the right of WTO members to protect public health and their population, in particular, in ensuring medicines for all their citizens. This declaration significantly changed the international scenario. Numerous countries and the international community as a whole have mobilized as a result, and Brazil has assumed responsibility in relation to other developing countries, in the name of international solidarity and cooperation, playing a leadership role in the process including policy issues, declarations, international resolutions, and effective work with the Global Fund to Fight AIDS, Tuberculosis, and Malaria.

International relations interfere in the dynamics of domestic policies, and Brazil inevitably depends on (and will experience) the results of this global mobilization. It would be unfeasible to deal with the international economic order without alliances, establishing partnerships and international mobilization. This historical process will thus reflect and contribute to the sustainability of the Brazilian Program. The AIDS pandemic will have a major impact in the coming decades, new drugs will continuously reach the market, and if there is no change in the world order in relation to intellectual property and marketing of medicines, Brazil's program may become unfeasible, or at least tremendously

costly for the country, on a level that will be absolutely unfair for our social and economic reality.

There is no doubt that Brazil's international leadership will bring positive consequences for its domestic policy. It is already evident that various sectors of Brazilian society have joined the Brazilian response to the AIDS epidemic. The struggle against AIDS in Brazil today is both presented and viewed as belonging to political leaders, government, the community, and the press. This shared ownership and responsibility is absolutely proper and desirable. It greatly increases the possibilities for maintaining and enhancing action against the epidemic, because AIDS has become a national cause.

THE GLOBAL FUND TO FIGHT AIDS, TUBERCULOSIS, AND MALARIA

The Global Fund to Fight AIDS, Tuberculosis, and Malaria was one of the concrete actions arising from the discussions launched at UNGASS. Again, Brazil's participation was key for comprehending the importance of large investments to fight the epidemic – not only financial investments, but also political ones, for building a new reality, consistent with the needs created by the AIDS pandemic, which means including the health issue on every human rights agenda. Brazil was one of the most active countries in setting up the Fund, especially in having the

UNGASS principles guaranteed and adopted. The country played a vital role in guaranteeing equitable participation by the various players involved in conducting the Fund and defining its mission, including treatment, multi-sector mobilization, and participation by CSO and people living with HIV/AIDS, tuberculosis, and malaria. The Fund is an international solidarity effort. If it succeeds in providing the means for expanding access to anti-retroviral therapy, with a resulting increase in international consumption of medicines, greater purchases of medicines, and broader agreements on differentiated prices, there will be an important impact on prices that will also be reflected in Brazil. Brazil has initially decided not to apply for resources from the Global Fund, given the situation in dozens of countries where public funds to fight these diseases are virtually non-existent.

This is the first time that an international fund has provided CSO and developing countries with voice and vote under the same conditions as donor countries. Traditionally, international funds such as the International Monetary Fund, the World Bank, the Vaccine Fund, and the Global Environmental Facility have been structured so as to guarantee that votes are proportional to the amount of the contribution by each respective country, thereby impeding beneficiary countries and civil society organizations from ex-

ercising greater activity in the management and disbursement of available resources.

The Global Fund to Fight AIDS, Tuberculosis, and Malaria – consisting of seven wealthy countries, seven developing countries, two CSO, and one representative each from the private sector and foundations – has emerged under a new paradigm, whereby the developing countries have the competence and the right to set their own policies to fight these diseases based on local demands and needs. There will thus be no priorities defined ahead of time by donors, as was usual until now. Again, Brazil's participation was crucial for developed countries to understand that the regional characteristics of AIDS and the political and social demands to confront the epidemic require that definitions be made in the sphere of the countries affected by it and not from the top down.

In the Global Fund's structure, Brazil represents Latin America and the Caribbean during the first two years. This decision was made by the countries of the region themselves, given that Brazil currently has both the other countries' trust and the greatest experience in fighting the epidemic.

The dynamics outlined for the Fund aim initially at prioritizing the countries that will apply for funds, taking a number of factors into account, including level of poverty, severity of the epidemic, and the

country's own level of mobilization. A prerequisite is that the project-formulating process should occur within the country itself. A local committee necessarily including government, civil society, and other stakeholders will analyze and establish local priorities, and the Fund will seek to meet what has been identified as essential by the countries.

IN SHORT...

We can identify important turning points in the fight against AIDS in Brazil. In 1983, installation of the first programs; in 1988, control of the blood bank system, the right to medicines for opportunistic infections and the initial work involving injection drug users. Another milestone was the year of 1992, with the political choice to sign a loan agreement between the Brazilian government and the World Bank, coinciding with the reformulation of the National STD/AIDS Program and including community participation. The year of 1996 witnessed the advent of triple therapy and the adoption of a domestic policy for universal access to all available treatment. And beginning in 2000, more organized, planned international action – such as the UNGASS in June 2001 – and the approval, in November of that same year, of a consensus paper in the WTO for the Separate Ministerial Declaration on TRIPS and Public Health.

Domestic and international recognition of Brazil's effort in the struggle against the AIDS epidemic can be seen as the greatest Brazilian victory in this struggle. Such recognition lends legitimacy to the Brazilian Program in the struggle against HIV/AIDS, and especially to the country's policy of free universal access to anti-retroviral drugs.