Health care to HIV/AIDS patients in Brazil

ABSTRACT

This study was intended to assess care provided to those living with HIV/AIDS in Brazil and the Brazilian Unified Health System (SUS) capacity of delivering interventions to cope with the epidemic as well as to discuss the sustainability of the Brazilian initiative of providing universal free access to antiretrovirals (ARVs). Original data from a study comprising 119 respondents on the potential capacity of delivering a prospective HIV vaccine in Brazil was used. Inpatient and pharmaceutical care was based on data from the SUS Hospital Information System and Drug Logistics Management Systems of the National Program for STD/AIDS. The study results indicate good performance of the Brazilian ARV Access Program but access to treatment of opportunistic infections was, however, unsatisfactory. The rates covered by SUS for AIDS hospital admissions remained very low, on average around R$700 in 2004. Health care to HIV/AIDS patients has been considered a citizen’s right strongly supported by an effective joint action of the Brazilian government and civil society. The current challenges are fine monitoring of processes and program results and ensuring sustainability of universal free ARV access.

INTRODUCTION

The Care, Support and Treatment principle of the United Nations Declaration of Commitment on HIV/AIDS addresses two main points. First, strengthening health care systems for safely and effectively providing antiretroviral (ARV) therapy and best care recommended for prevention and treatment of opportunistic infections, including actions on drug practices and policies that would allow a sustainable ARV provision. Second, developing and progressively implementing comprehensive strategies for care and support, including psychosocial support, to those individuals, families and communities living with HIV/AIDS, on a family or community basis or at the level of health care services.

The commitment agreements endorsed for 2003 and 2005 have already been incorporated to the guidelines developed by the Brazilian government. The Brazilian Health System first provided drug for opportunistic infection treatment in 1988, and zidovudine became available in 1991. In 1996, the government took a groundbreaking step and pioneered passing a law establishing as the State’s responsibility to provide universal free drugs for the treatment of HIV/AIDS patients. In addition, the National Program for STD/HIV/AIDS (PN-DST/AIDS) has been historically characterized by taking thorough care measures and incorporating comprehensive strategies to fight against the epidemic and having a central role in promoting joined action with civil society.

Measuring the achievement of the established targets goes beyond the simple formal verification of their attainment. It poses challenges that indicate the need for finer monitoring of processes and results of care provided to those living with HIV/AIDS concerning drug therapy, and health services utilization as well as attention at the community level. It also raises questions on quality of care provided through actions of a distinctive National Program, unique in many aspects but still relying on the Brazilian care system undermined by serious operational problems. Ultimately, it brings about issues on the government agenda on how to assure sustainable drug access programs to those living with HIV/AIDS given their rising costs.

While most issues outlined above still need to be further explored and appraised, some have already been studied. HIV/AIDS outpatient care was assessed in a study conducted in seven Brazilian states – Pará, Maranhão, Ceará, Rio de Janeiro, São Paulo, Rio Grande do Sul and Mato Grosso do Sul –, in 2001 and 2002 and recently published by the QualiAids Project group.

The present study intended to further address other aspects of care provided to those living with HIV/AIDS in Brazil, including an overall assessment of the health system capacity to fight the epidemic; a descriptive outlook on hospital admission rates in the Brazilian Unified Health System (SUS) in recent years; and an input on the impact and sustainability of universal free access to ARVs.

SOURCE OF DATA ANALYZED

Data were collected from several sources, and unpublished results are presented as well as previously published results from other studies and documents.

The overall assessment of the capacity for implementing interventions on HIV/AIDS is based on original data from a 2005 research study on the potential capacity for providing a prospective anti-HIV vaccine in Brazil, as proposed by the World Health Organization (WHO). Data were collected from interviews with 119 subjects, including managers of the PN-DST/AIDS, local and state representatives of STD/AIDS program, representatives of non-governmental organization (NGOs), investigators, and HIV/AIDS health providers. A total of 12 HIV interventions were evaluated and their scores ranged from 0 to 10 and comprised items such as prophylactic treatment to HIV exposed health providers, access to primary and secondary prophylactic treatment to opportunistic infections, access to opportunistic infection treatment and effective population-based HIV/AIDS treatment programs.

Hospital and drug care aspects included in the Brazilian ARV access program intertwine when analyzing data from SUS Hospital Information System (SIH)** and the PN-DST/AIDS Drug Logistics Management System (SICLOM). HIS data comprise all admissions in public and private (contracted and philanthropic) hospitals covered by SUS at national level and include variables such as demographic (age and gender), clinical diagnosis and those related to health services utilization (length of hospital stay, intensive care unit admission, procedures).

When SUS costs, hospital admission rates and patients
Table 1 - Assessment of the capacity of implementing HIV interventions. Brazil, 2005.

<table>
<thead>
<tr>
<th>Intervention</th>
<th>N</th>
<th>Mean</th>
<th>Standard deviation</th>
<th>Min.</th>
<th>Median</th>
<th>Max.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Public efforts for HIV knowledge</td>
<td>119</td>
<td>7.6</td>
<td>1.8</td>
<td>3</td>
<td>8</td>
<td>10</td>
</tr>
<tr>
<td>Promotion/distribution of condoms</td>
<td>119</td>
<td>7.0</td>
<td>1.9</td>
<td>1</td>
<td>7</td>
<td>10</td>
</tr>
<tr>
<td>Promotion of safe injecting drug use</td>
<td>114</td>
<td>4.8</td>
<td>2.0</td>
<td>0</td>
<td>5</td>
<td>10</td>
</tr>
<tr>
<td>Access to HIV counseling/voluntary testing</td>
<td>119</td>
<td>6.6</td>
<td>1.7</td>
<td>2</td>
<td>7</td>
<td>10</td>
</tr>
<tr>
<td>Access to STD testing and treatment</td>
<td>118</td>
<td>5.8</td>
<td>1.8</td>
<td>2</td>
<td>6</td>
<td>10</td>
</tr>
<tr>
<td>Access to prevention of vertical transmission</td>
<td>118</td>
<td>6.6</td>
<td>1.9</td>
<td>2</td>
<td>7</td>
<td>10</td>
</tr>
<tr>
<td>Access to patient-based behavioral counseling</td>
<td>117</td>
<td>5.8</td>
<td>2.0</td>
<td>1</td>
<td>6</td>
<td>10</td>
</tr>
<tr>
<td>Campaigns for promoting safe sex targeting adolescents, women, etc.</td>
<td>119</td>
<td>6.3</td>
<td>1.9</td>
<td>0</td>
<td>7</td>
<td>10</td>
</tr>
<tr>
<td>Prophylaxis to HIV exposure for health providers</td>
<td>116</td>
<td>6.5</td>
<td>2.0</td>
<td>0</td>
<td>7</td>
<td>10</td>
</tr>
<tr>
<td>Access to primary and secondary opportunistic disease prophylaxis</td>
<td>119</td>
<td>6.4</td>
<td>2.1</td>
<td>0</td>
<td>7</td>
<td>10</td>
</tr>
<tr>
<td>Access to opportunistic infection treatment</td>
<td>118</td>
<td>6.4</td>
<td>2.1</td>
<td>0</td>
<td>6.5</td>
<td>10</td>
</tr>
<tr>
<td>Effective wide scale HIV/AIDS treatment programs</td>
<td>118</td>
<td>7.1</td>
<td>2.0</td>
<td>0</td>
<td>8</td>
<td>10</td>
</tr>
</tbody>
</table>

Figures and tables

CAPACITY TO FIGHT THE EPIDEMIC

Table 1 shows the results of the assessment of the capacity for implementing interventions on HIV/AIDS. Specifically, the last items are focused in the aforementioned principle of the UN Declaration of Commitment on HIV/AIDS: prophylaxis and HIV exposure of health providers; access to primary and secondary prophylaxis to opportunistic infections; access to opportunistic infection treatment; and implementation of effective HIV/AIDS treatment national programs. Although means are slightly low because of several very negative evaluations, medians indicate relatively favorable evaluations, especially concerning the implementation of effective HIV/AIDS treatment national programs (median = 8). Of the four aspects highlighted, access to opportunistic infection treatment had the poorest evaluation.

Though ARVs are provided by SUS services, SICLOM includes treatment registry data from both public and private sectors, which allowed estimating that 90.5% of patients actually receive care in SUS. This finding puts into context the counterpoint between hospital admission rates and costs covered by SUS and ARV provision, which pervades the following results.

Figure 1 shows the heavy burden of ARVs to the total public AIDS costs, where as it shows a relative stability of, at least overall, hospital care expenditures.

HOSPITAL ADMISSION RATES IN THE SUS

Figure 2 illustrates detailed expenditures by SUS for HIV/AIDS hospital care, including hospital admissions as such and day hospita-
tal care, ranging from slightly less than R$20 million in 1998 to about R$27.3 million* in 2004. The South-
eastern region had the largest share which, rather con-
sistently, showed the lowest mean cost per hospital 
admission in this period (Figure 3). Nationwide, the 
mean AIDS admission cost ranged from approximately 
R$550 in 1998 to R$700 in 2004. The highest mean 
costs were seen in the Northern and Southern regions.

Figure 4 displays the number of AIH for AIDS care 
issued between 1998 and 2004, by regions. There 
was a non-significant growth of total admissions 
countrywide, which is translated by a difference of 
less than 5,000 hospital admissions between 1998 
and 2004. In regard to regions, Figure 4 shows rela-
tively significant growth in the Northern, Northeast-
er and Midwestern regions, which contrasts 
with declining rates in the Southeastern re-
gion.

The ratio estimate between the number of AIDS 
hospital admission and total admissions cov-
ered by SUS could be slightly masked by AIH 
for day hospital care. Figure 5 indicates high 
hospital admission rates in the Southeastern 
and Southern regions, however declining in 
the former and still growing in the latter. In the 
Northern, Northeastern and Midwestern re-
gions, the observed rates are dramatically lower 
with mostly increasing trends in 2004, show-
ing two AIDS admissions per 1,000 SUS ad-
missions.

Figure 6 depicts a direct analysis of HIV/AIDS 
admission distribution (N=28,163), by re-
gions and SUS hospital categories in 2004, 
making a distinction between inpatients and 
day hospital care. It is noted the high share of 
state (44.2%) and philanthropic hospitals (25.0%). In contrast, the fact that there are no 
registries of university hospital admissions 
could be explained by a set financial ceiling 
on SUS payment to hospitals. It also sug-
gests a reversal of the trend seen in the last 
decade when university hospitals were the main 
providers of AIDS care.

Still based on data from hospital admissions covered 
by SUS in 2004, Table 2 displays the distribution of 
the variables “costs and length of stay according to 
main diagnosis,” defined by the International Classi-
fication of Diseases – 10th revision (ICD-10) for regu-
lar hospital admissions. Basically descriptive, data 
on Table substantiate low payment of HIV/AIDS hos-
pital admissions by SUS.

Based on data on provision of drugs registered in 
SICLOM between 1998 and 2003, there has been a 
gradual increase in adequate ARV therapeutic regi-
mens according to the recommendations (Figure 8). 
SICLOM data provides longitudinal monitoring of 
ARV provision and dynamic as well as a registry of 
all patients receiving ARVs. This system has not yet

*In May 2006, US$1 =R$2,10
been fully implemented to allow for following up all patients on therapy.

Figures 9 and 10 show AIDS hospital admission rates and social security benefits to those patients receiving ARVs in the period between 1998 and 2004 and between 1997 and 2001, respectively. The clearly declining rates are suggestive of the effectiveness of ARV access programs.

**Figure 5** - Number of AIDS admissions per 1,000 admissions covered by SUS by regions and nationwide. Brazil, 1998–2004.

Sources: Datasus; Sistema de Monitoramento de Indicadores do Programa Nacional de DST/Aids - MONITORAIDS. Disponível em http://www.aids.gov.br [acesso em 1 mar 2006]

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The interiorization and pauperization of AIDS epidemic in Brazil represents a challenge and calls for the results attained in main urban centers to be extensive to all other regions and social segments. Brazil should be involved in discussions on the utilization of intervention models based on more practical and less complex technologies that will ensure satisfactory results in health settings with less developed infrastructure that are not easily accessible to different populations.

While compliance to ARV therapy is 75%,* which is consistent with that seen in developed countries, it is imperative to find new ways of scaling up actions for compliance promotion through improving health services, building up capacity of multidisciplinary teams and supporting joined activities of health services with local community.

Improving quality of care provided by a distinctive National Program for STD/AIDS, unique in many aspects, but that relies on the strengthening of Brazilian care system in all levels, should be a concern. The Brazilian health care system is undermined by serious operational problems and several different local realities, many of them below the desired care standards.

**Figure 6** - HIV/AIDS hospital admissions covered by SUS (N=28,163) by regions and hospital categories. Brazil, 2004.

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HIV/AIDS outpatient care comprises services with heterogeneous settings and infrastructures that mostly are in easily accessible areas and have the minimum required resources. In their study, Melchior et al. reported that 74% of all outpatient care units had at least one infectious disease specialist available and 90.4% had at least one non-medical provider, and 76% of health teams consisted of a social worker, a nurse, a psychologist and a pharmacist. The majority of health units had in place referral mechanisms to direct patients to other specialties within the SUS. However, some specialty services require long waiting hours, and referrals to pneumologists, neurologists, eye specialists and general surgeons are the most troublesome. CD4 and CD8 counts and viral load tests as well as regular laboratory tests and X-rays were available in more than 95% of services but there was increased difficulty in having access to more complex testing, especially imaging tests. ARVs were consistently highly available, contrasting with low access to other drugs for opportunistic infection prophylaxis and treatment. With heterogeneous settings and infrastructures. Our findings are consistent with studies performed in other Brazilian regions. However, some specialty services require long waiting hours, and referrals to pneumologists, neurologists, eye specialists and general surgeons are the most troublesome. CD4 and CD8 counts and viral load tests as well as regular laboratory tests and X-rays were available in more than 95% of services but there was increased difficulty in having access to more complex testing, especially imaging tests. ARVs were consistently highly available, contrasting with low access to other drugs for opportunistic infection prophylaxis and treatment. With heterogeneous settings and infrastructures. Our findings are consistent with studies performed in other Brazilian regions. However, some specialty services require long waiting hours, and referrals to pneumologists, neurologists, eye specialists and general surgeons are the most troublesome. CD4 and CD8 counts and viral load tests as well as regular laboratory tests and X-rays were available in more than 95% of services but there was increased difficulty in having access to more complex testing, especially imaging tests. ARVs were consistently highly available, contrasting with low access to other drugs for opportunistic infection prophylaxis and treatment. With heterogeneous settings and infrastructures. Our findings are consistent with studies performed in other Brazilian regions.

**Table 2** - Costs and length of hospital stay for HIV/AIDS patients covered by SUS according to main diagnosis. Brazil, 2004.

<table>
<thead>
<tr>
<th>ICD-10 Description</th>
<th>N</th>
<th>%</th>
<th>Mean</th>
<th>Standard deviation</th>
<th>Minimum</th>
<th>Median</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>B20.0 HIV disease resulting in mycobacterial infection</td>
<td>3,358</td>
<td>11.9</td>
<td>Costs (R$)</td>
<td>902 620</td>
<td>87</td>
<td>743</td>
<td>10,158</td>
</tr>
<tr>
<td>B20.1 HIV disease resulting in other bacterial infections</td>
<td>2,486</td>
<td>8.8</td>
<td>Length of stay (days)</td>
<td>19 20</td>
<td>0</td>
<td>13</td>
<td>256</td>
</tr>
<tr>
<td>B20.2 HIV disease resulting in cytomegaloviral disease</td>
<td>101</td>
<td>0.4</td>
<td>Costs (R$)</td>
<td>778 435</td>
<td>272</td>
<td>634</td>
<td>2,595</td>
</tr>
<tr>
<td>B20.3 HIV disease resulting in other viral infections</td>
<td>564</td>
<td>2.0</td>
<td>Costs (R$)</td>
<td>800 677</td>
<td>272</td>
<td>558</td>
<td>7,343</td>
</tr>
<tr>
<td>B20.4 HIV disease resulting in other specified infections</td>
<td>502</td>
<td>1.8</td>
<td>Length of stay (days)</td>
<td>17 26</td>
<td>0</td>
<td>11</td>
<td>368</td>
</tr>
<tr>
<td>B20.5 HIV disease resulting in other mycoses</td>
<td>192</td>
<td>0.7</td>
<td>Costs (R$)</td>
<td>908 906</td>
<td>136</td>
<td>660</td>
<td>7,969</td>
</tr>
<tr>
<td>B20.6 HIV disease resulting in Pneumocystis carinii pneumonia</td>
<td>1,900</td>
<td>6.8</td>
<td>Length of stay (days)</td>
<td>18 17</td>
<td>1</td>
<td>11</td>
<td>110</td>
</tr>
<tr>
<td>B20.7 HIV disease resulting in multiple infections</td>
<td>2,837</td>
<td>10.1</td>
<td>Costs (R$)</td>
<td>1,065 639</td>
<td>272</td>
<td>803</td>
<td>8,630</td>
</tr>
<tr>
<td>B20.8 HIV disease resulting in infectious and parasitic diseases</td>
<td>2,444</td>
<td>8.7</td>
<td>Length of stay (days)</td>
<td>21 22</td>
<td>0</td>
<td>14</td>
<td>371</td>
</tr>
<tr>
<td>B20.9 HIV disease resulting in unspecified infectious or parasitic disease</td>
<td>1,331</td>
<td>4.7</td>
<td>Costs (R$)</td>
<td>887 915</td>
<td>272</td>
<td>602</td>
<td>14,766</td>
</tr>
<tr>
<td>B21.2 HIV disease resulting in other types of non-Hodgkin’s lymphoma</td>
<td>36</td>
<td>0.1</td>
<td>Length of stay (days)</td>
<td>19 22</td>
<td>0</td>
<td>13</td>
<td>380</td>
</tr>
<tr>
<td>B22.0 HIV disease resulting in encephalopathy</td>
<td>2,153</td>
<td>7.6</td>
<td>Costs (R$)</td>
<td>1,110 947</td>
<td>87</td>
<td>834</td>
<td>13,561</td>
</tr>
<tr>
<td>B22.1 HIV disease resulting in lymphoid neoplasms</td>
<td>525</td>
<td>1.9</td>
<td>Costs (R$)</td>
<td>878 949</td>
<td>272</td>
<td>607</td>
<td>11,726</td>
</tr>
<tr>
<td>B22.2 HIV disease resulting in wasting syndrome</td>
<td>30</td>
<td>0.1</td>
<td>Costs (R$)</td>
<td>630 305</td>
<td>258</td>
<td>513</td>
<td>1,919</td>
</tr>
<tr>
<td>B23.0 Acute HIV infection syndrome</td>
<td>311</td>
<td>1.1</td>
<td>Length of stay (days)</td>
<td>15 15</td>
<td>1</td>
<td>9</td>
<td>63</td>
</tr>
<tr>
<td>B23.1 Acute HIV infection syndrome</td>
<td>114</td>
<td>0.4</td>
<td>Costs (R$)</td>
<td>719 299</td>
<td>272</td>
<td>741</td>
<td>2,900</td>
</tr>
<tr>
<td>B23.2 HIV disease resulting in haematological and immunological abnormalities, not elsewhere classified</td>
<td>1,935</td>
<td>6.9</td>
<td>Length of stay (days)</td>
<td>17 17</td>
<td>1</td>
<td>13</td>
<td>125</td>
</tr>
<tr>
<td>B23.3 HIV disease resulting in other specified conditions</td>
<td>7,159</td>
<td>25.4</td>
<td>Costs (R$)</td>
<td>936 816</td>
<td>27</td>
<td>667</td>
<td>12,984</td>
</tr>
<tr>
<td>B23.4 Unspecified HIV disease</td>
<td>75</td>
<td>0.3</td>
<td>Length of stay (days)</td>
<td>16 19</td>
<td>1</td>
<td>9</td>
<td>99</td>
</tr>
</tbody>
</table>

This Table includes only diagnoses reported in at least 30 hospital admissions covered by SUS in 2004.
laxis and treatment. This practice follows current internationally recommended evidence-based clinical guidelines and these recommendations are periodically updated and disseminated nationwide.*

The positive impact of a comprehensive health care program to those living with HIV/AIDS in Brazil is patent. Studies reported significantly improved survival rates of those living with HIV/AIDS.8,12 On the other hand, where as the absolute rates of HIV/AIDS hospital admissions remained stable in the period between 1998 and 2004, the number of those receiving ARVs was significantly reduced, indicating an increase in patients on therapy, early diagnosis, higher survival rates and, ultimately, improved general health condition of these patient.

Translating reduced hospital admission rates in economic terms is strongly appealing but this is prevented by the very low SUS coverage. Assuming in 2004 the same hospital admission rates of ARV patients as in 1998 and mean cost of R$ 700 per admission, it can be roughly estimated that, in 2004, more than 57,000 admissions were prevented, a saving of approximately R$ 40 million to SUS. It should be noted, however, that these figures do not provide a measurement of efficiency of ARV access program in Brazil, to be determined through a careful economic evaluation. Effectiveness data, translated into increased survival and quality of life, are much more compelling. Moreover, it should be emphasized, no demerit, the decision to implement such program was essentially political, grounded on the perception of it as a human and legal right of Brazilian population, strongly supported by the joined action of the PN-DST/AIDS with local and state authorities and the organized civil society.2,7

As for sustainable access to ARV therapy, the UN Declaration of Commitment on HIV/AIDS recognized the need for reducing ARV costs and the impact of free trade agreements on local essential drug manufacturing on the development of new drugs.

The Brazilian government has been making efforts to ensure sustainable universal access to ARVs now provided to around 170,000

people at an annual cost of about US$450 million. This program comprises strategies of national manufacturing of non-patented drugs, negotiating prices with drug companies and playing a role internationally for changing regulations on intellectual property and access to drugs. Between 1997 and 2004, there was a 4.6 time reduction in the mean ARV treatment cost, from US$6,2 to 1,300.

However, since 2005, the declining cost trend has changed. The Brazilian Ministry of Health estimates significantly increasing mean treatment costs due to a proportional reduction of first line drug use, which are locally manufactured and have an average cost of about US$600 per year per patient, and increased second line therapies, all imported and patent protected. ARV import currently accounts for 80% of government ARV budget and this situation tends to be aggravated if budget and this situation tends to be aggravated if significantly increasing mean treatment costs due to a proportional reduction of first line drug use, which are locally manufactured and have an average cost of about US$600 per year per patient, and increased second line therapies, all imported and patent protected. ARV import currently accounts for 80% of government ARV budget and this situation tends to be aggravated if budget and this situation tends to be aggravated if

Table 3 - Relevant facts on universal free ARV Access Program to HIV/AIDS patients in Brazil.

<table>
<thead>
<tr>
<th>Year</th>
<th>Relevant facts</th>
</tr>
</thead>
<tbody>
<tr>
<td>1988</td>
<td>The new Brazilian Constitution creates the Unified National Health System (SUS) recognizing health care as a basic citizen right.</td>
</tr>
<tr>
<td>1991</td>
<td>The Brazilian government begins providing free zidovudine (AZT).</td>
</tr>
<tr>
<td>1995</td>
<td>Brazil starts to produce ARVs.</td>
</tr>
<tr>
<td>1996</td>
<td>Law establishing free provision of ARVs to those living with AIDS.</td>
</tr>
<tr>
<td>2001</td>
<td>Brazil threatens to break ARV patents employing compulsory licensing, a provision established by the Brazilian Intellectual Property Law.</td>
</tr>
<tr>
<td>2003</td>
<td>Decree facilitating import of generic drugs produced under compulsory licensing.</td>
</tr>
<tr>
<td>2004</td>
<td>Negotiations between the Brazilian government and multinational pharmaceutical companies.</td>
</tr>
<tr>
<td>2005</td>
<td>Bill establishing AIDS drugs as non-patentable.</td>
</tr>
</tbody>
</table>

In addition, the generic AIDS drug program adopted by Brazil is based on strengthening public laboratories for allowing them to develop other drugs essential to public health. But uncoordination between national public drug manufacturers’ efforts, development of new technologies and research promotion have aggravated in recent years despite considerable investments by the Ministry of Health on infrastructure and equipment. Consequently, combined to slow rigid administrative and legal bureaucratic bidding processes, in 2004 and 2005, there was ARV undersupplying, projects for new drug development were delayed, including those drugs associated at fixed doses, and the sustainability of the PN-DST/AIDS and quality of care provided to those living with HIV/AIDS were jeopardized.

In conclusion, International Trade Agreements are not compatible with public health needs of Southern hemisphere countries for research promotion, technological development, strengthening of national industries and universal free access to health services. In Brazil, in addition to the fact that there is no properly defined strategy for research and development, international laws have deterred reverse engineering for developing second line drugs and, hence, the national drug industry. Local governments have not taken any actions to guarantee compliance with Article 68 of the Industrial Property Law, which determines that drugs can be locally manufactured three times that drugs can be locally manufactured.


years after they have been registered. The government has not either applied TRIPS flexibilities favoring the local industry. All ARV cost negotiations conducted by the Ministry of Health with patent holder multinational drug companies produced lower price agreements. However, these agreements did not include provisions concerning technology transfer and voluntary licensing and thus have not been an actual encouragement to local public and private drug manufacturers. Brazil has actively been involved advocating that free trade agreements under negotiation should not include restrictive provisions concerning intellectual property, referring to TRIPS agreement and Doha Declaration as the highest commitment with intellectual property issues. Internationally, Brazil has also headed a so-called movement “Friends for Development,” questioning the impact of patents on drug research and development and access to drugs in the World Intellectual Property Organization (WIPO). Brazilian and Argentine leadership contend to prevent the implementation of patent agreements under negotiation as they would jeopardize the sovereignty of developing nations.

In 2003, the Brazilian government changed the legislation to allow generic drug imports under compulsory licensing nationwide. In 2005, the Lower House passed a bill establishing all AIDS drugs as non-patentable therapies.* This bill is now under scrutiny in the Brazilian Senate for approval.

Efforts are expected to be made to overcome the difficulty created by the Bidding Law 8.666, which determines rotation of producers providing raw material to government laboratories and hinders the registry of drugs as generic. This is so despite adequate bioequivalence evaluations and proper local regulations for registry and control of locally manufactured drugs, including an actively involved National Agency of Health Surveillance (ANVISA).

REFERENCES


