

COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INNOVATION AND PUBLIC HEALTH

BACKGROUND DOCUMENT FOR 3rd COMMISSION MEETING Brazil, 31 January - 4 February 2005

This document is intended to accompany the Agenda for the CIPIH Brazil visit. It is divided into two parts: the first provides basic background about issues in the Brazilian context relevant to the Commission's work, whilst the second part describes major institutions operating within this environment, whose representatives will meet with CIPIH during the course of its visit. The Secretariat is grateful to the Government of Brazil, WHO's Country Representatives in Brazil, and WHO's PAHO Office for their collaboration and invaluable assistance in the preparation of this meeting.

PART 1: BACKGROUND

Introduction

Brazil has a surface area of 8,514,876,599 km²¹, and a population of 178,985,000 inhabitants, predominantly urban (83%) and young, with 27.96% of the population being 14 years of age or less, 65.86% within the range of 15 to 64 years of age and 6.18% being 65 years of age or more². There was an increase of life expectancy, which reached 69 years of age in 2003. Brazil is the largest and most populous country of South America. In 2003, according to the Institute of Economics Applied Research (IPEA), the GDP per capita was US\$2,824³.

Brazil has one federal district, 26 states and 5,560 townships¹; most of its population lives in the South, South West and North East parts of the country. Brazil has vast natural resources, including the rain forests of the Amazon, a considerable labour pool, and large, well-developed agricultural, mining, manufacturing and service sectors.

According to the 2003 Human Development Report, published by the United Nations Development Program, Brazil occupied the 65th position in the HDI ranking. Among the achievements observed, the text highlights that there were improvements in access to education, with an equal number of boys and girls now registered in schools⁴. There are positive references regarding initiatives which are considered as "success stories" in the country, with a highlight on the fight against AIDS and "Fome Zero" programs. The report also points to the persistence of inequalities among the regions, and the growing tendency of income concentration: the GINI Index reached 0.61, and the richest decile (10%) of households in Brazil hold 70 times the income of the bottom 10% of households. The report also states that, although there has been a decrease in the number of people living below the poverty line in the regions, the Northern region registered an increase in poverty, going from 36% in 1990 to 44% of the population in 2001, and emphasizes that the maintenance of this tendency will prevent the Country from reaching the goal of poverty reduction of 50% by 2015³.

The Health Information Inter-Agency Network (RIPSA)ⁱ identified 39% of the population living in a state of poverty in the Northern Region in 2003. The figure for the entire country is 31%.

Besides its status as an economic leader within South America, Brazil has emerged as an influential player in the global areas of finance and trade. For instance, the Brazilian Government has initiated discussions with India and South Africa (IBSA), with the aim of developing joint actions in a number of domains. The three countries are also pushing together for an expanded Security Council at the United Nations, in which they would hold permanent seats. President Luiz Inácio Lula da Silva recently made a three-day visit to India to build a "new trade geography" in the world, to create new alternatives, reduce dependence and unite developing countries to negotiate equal conditions.

National Public Health System

Universal access to health services is a central tenet of the country's Constitution, according to which, "Health is a right of all and a duty of the State and guaranteed by means of social and economic policies aimed at reducing the risk of illness and other hazards and all the universal and equal access to actions and services for its promotion, protection and recovery".

The Brazilian Health Reform process represents a significant change in the access condition, in the institutional apparatus and in the financing mechanisms of the health system of the country. The implementation of the Unified Health System (SUS) involves the institutional unification of the system at the federal level and decentralization of the system, with the implementation of a regionalized public network. The SUS is being implemented in accordance with the following principles: universality; integrality; decentralization; social participation; and equality of access rights for all citizens to health actions and services, at all levels of complexity. The private network of health services can participate as a complement to the SUS. The private services are autonomous, although submitted to regulation, audit and control by the State, where health actions and services are considered of "public relevance" by the Constitution's text⁵

In 2003, according to the RIPSA, there were 1.42 doctors per 1000 inhabitants³ in Brazil. The Medical Sanitary Assistance Survey (AMS) of the Brazilian Institute of Statistics and Geography (IBGE) registered the existence of 53,825 healthcare establishments in the country in 2002 (excluding those focused on diagnostic and therapeutic support). Out of these, 13.7% were establishments with inpatient facilities, where the presence of the private sector is relevant: 65% of hospitals are private. On the other hand, 76% of establishments without inpatient facilities are public.

In July 2003, according to the SUS Information and Informatics Department - DATASUS, there were available, through the SUS, 441,591 hospital beds, out of which 62.7% were private and 27.9% public. These beds represent 80% of existing beds in the Country.

ⁱ Based on the information of the National Institute of Geography and Statistics/National Research of Household Sampling (IBGE/PNAD, 2003).

The regulation of private health services is the responsibility of the National Agency of Supplementary Health (ANS). In December 2003, 38 million persons were covered by private health insurance⁶. In 2001, Brazil's health expenditure was 8.5% of GDP⁷.

In early 1997, Brazil's Ministry of Health established a working group to coordinate the development of a national drug policy. The resulting "National Drug Policy" document, the product of 20 months of broad negotiation, was adopted in 1998, and represented Brazil's first drug policy consistent with WHO guidelines. The document established a basis for activities and priorities, including the adoption of a national essential medicines list, health-related regulation of medicines, the re-orientation of pharmaceutical services, and promotion of the rational use of drugs, scientific and technological development, the promotion and production of pharmaceuticals, and human resources development⁸. In addition, the National Policy of Pharmaceutical Services⁹ was approved in 2004. The National List of Essential Medicines (RENAME), based on WHO's model drug list, is reviewed regularly by a national commission. The RENAME's latest revision is from 2002, and currently lists 520 formulations of 327 drugs¹⁰.

There is an agreement regarding Pharmaceutical Services for Primary Healthcare with a minimum shared financing by the Federal Government (US\$ 0,37/per capita per annum), State and Municipal (at least US\$ 0,18 / per capita per annum each) with a list of drugs based on RENAME that must be available for dispensing in the primary healthcare units. There is a Federal Program for Hypertension and Diabetes, with 5 medicines provided by the Health Ministry, for patients registered in these programs. There is also a program for Mental Health financed 80% by the MOH and 20% by the State Secretary of Health¹¹.

The federal government provides medicines for enrolled patients in the treatment of specific diseases, such as HIV/AIDS, Tuberculosis, Hanseniasis, Blood and Hemoderivatives (Factor VII, Factor IX, Protrombinic and Desmopressine Complex), Diabetes (Insuline) and Endemic Control (Drugs for the treatment of Chagas Illness, Schistosomosis, Filariosis, Leishmaniosis, Malaria, Pest and Trachoma). The programming of needs, storage, distribution, stock control and distribution of drugs is a responsibility of States and Townships.

In Brazil, the availability of Drugs in the Unified Health System (SUS) is not restricted to the medicines included in the the National List of Essential Drugs, there are also the so-called Exceptional/High-cost medicines. According to the National Council of State Secretaries of Health (CONASS), the Exceptional Medicines Programme is responsible for the group of medicines destined for the treatment of specific pathologies which affect a limited number of patients, and which, in the majority of cases, are for long-term use¹¹. In 2003, a High-Complexity Medicines List was developed by the Ministry of Health which is made up of 106 drugs, with 218 formulations. Out of this total, 22 form part of RENAME. These high-cost drugs are utilized in the treatment of complex illnesses and its descriptions are defined by the Ministry of Health according to a series of Clinical Protocols. They are acquired by the State Secretariat of Health (SES), who is reimbursed by the Ministry of Health, through the High-Cost Payment Authorization (APAC).

Several States and Townships provide additional essential medicines in their healthcare services. One of the main challenges for the management of the drug supply in the Brazilian healthcare system is related to the guarantee of access to medicines to support the secondary level of the healthcare system. There is no official information available regarding regular access of medicines in Brazil.

Since 2004, a program called “Farmácia Popular do Brasil” (Popular Pharmacy of Brazil) has been in operation. In this program, the Oswaldo Cruz Foundation (FIOCRUZ), a body of the Ministry of Health and program executor, acquires drugs from the public or private pharmaceutical laboratories (as much as is required) and then sells them at the 27 Popular Pharmacies (in five states) with a low price. In all, there are 88 drugs with 91 formulations, as well as condoms¹².

The estimate for Public Expenditure of the Ministry of Health allocated to drugs in 2002 was US\$ 1,381,077,967.72. These figures do not include amounts allocated to drugs paid by States and Townships. Since the implementation of health’s decentralization process, the Union ceased to be the sole responsible agent for the financing and health assistance provision to the population, sharing it with the state and township health administrators, who are co-responsible for the financing and supply of medicines and for pharmaceutical services. No data was obtained regarding the amount spent by each state or township¹¹.

In 2003, the National Conference of Medicines and Pharmaceutical Services took place in Brasília, with the central theme: “Access, quality and humanization of Pharmaceutical Services with participation of the community”. At the national level 906 delegates (who participated previously in the 26 State and Township Conferences) participated, from all over the country, along with invited experts, observers and representatives from national bodies, giving a total of 1,180 participants¹³.

Patents, TRIPS and Post-2005

Contrary to public perceptions, there is a long history of intellectual property protection in Brazil. In fact, Brazil was one of the 14 countries that signed the original Paris Convention of 1883, which established the basic premises for the international industrial property system. Brazil provided patent protection for pharmaceutical products and processes until 1945 when legislation changed to exclude inventions containing food or pharmaceutical substances obtained by chemical means.

Comment [i1]: According to GIPI – the original agreement was signed by: Bélgica, Brasil, El Salvador, Equador, Espanha, França, Guatemala, Holanda, Inglaterra, Itália, Portugal, Sérvia, Suíça e Tunísia.

In 1969, further legislative changes excluded patent protection for pharmaceuticals (for applications deposited after the issue of the intellectual Property Code (CPI)). The landscape altered again when Brazil's new Industrial Property Law, of 1996, took full effect in 1997, achieving early compliance with the TRIPS Agreement, including patent protection on pharmaceutical products. According to that new legislation, compulsory licenses can be issued on the grounds of an abuse of intellectual property rights, abuse of economic power, dependent patent, or in cases of national emergency or public interest. In 2001, the Law was amended to make provisions concerning the results from the panel between Canada and the European Union related to patent protection of pharmaceutical products, and also the involvement of ANVISA (Brazilian Sanitary Surveillance Agency)

in the process of granting pharmaceutical patents.

On February 1st, 2001, the United States filed a complaint with the WTO claiming that art. 68 of Brazil's Industrial Property Law discriminated against imports, by allegedly violating Articles 27 and 28 of the TRIPS Agreement. The United States did not pursue its complaint, and an understanding was reached based on the commitment "to hold prior talks with the United States with sufficient advance notice to permit constructive discussions in the context of a special session of the US - Brazil Consultative Mechanism, should Brazil deem it necessary to apply Article 68 to grant a compulsory license on patents held by U.S. companies"¹⁴

General R&D Capacity

In 2004, according to Brazilian Federation of Pharmaceutical Industry (FEBRAFARMA)¹⁵, annual pharmaceutical sales in Brazil totaled US\$ 6.14 billion. Nevertheless, Brazil imported, that same year, US\$ 1.6 billion in pharmaceutical products, and exports US\$ 314 million, mostly to its neighbors, showing that the country is still highly dependent on imports. Imports from the United States account for about half of Brazil's pharmaceutical imports.

The pharmaceutical market in Brazil is highly fragmented, such that no single company has more than 5% of the market. Since companies tend to specialize in therapeutic markets, this decreases the overall level of competition. The pharmaceutical sector in Brazil is changing in its organization, financing and delivery of basic medications. Formerly, the purchase and distribution of drugs was managed by a central body; today there is an increasing role in the management of drug supply by states and municipalities. In 1998, the National Agency of Sanitary Surveillance (ANVISA) was created, to oversee the quality of health products and services, including pharmaceuticals. Its mission is "To protect and promote the population's health, ensuring the health safety of products and services, and participating in the construction of access to them"¹⁶.

The Price Regulation Policy was established in Brazil by the Medicines Market Regulation Chamber (CMED), an inter-ministerial body composed of the Ministry of Health (president), Treasury, Justice, Development and Civil House. The CMED has two levels of decision-making, the Ministry Council and the Executive Technical Committee. ANVISA has the role of secretariat.

The CMED establishes the limit for the annual changes in the prices of medicines. The prices of new medicines/products and new formulations have to be approved by the CMED, before marketing¹⁷. The medicines to be released are classified in six categories:

1. New molecules with benefits for the treatment, in relation to existing therapeutic options: the price cannot be higher than the lower price in nine countries;

2. New molecules with no benefits for the treatment, in relation to existing therapeutic options: the cost of the treatment cannot be higher than the cost of the other treatments available in the country;
3. New formulations for medicines in the market from the same manufacturer: the criteria is the average of the price of the medicines of the manufacturer;
4. New formulations for medicines in the market from different manufacturers: the criteria is the average price of the medicines from the other manufacturers;
5. New combination of active ingredients or formulation in the country: the cost of the treatment cannot be higher than the existing therapeutic options;
6. Generic drugs: the price has to be at least 35% lower than the reference medicine.

Homeopathic, herbal and some over-the-counter medicines are not included in this price control scheme.

According to Febrapharma, there were four income groups in Brazil, corresponding to Income groups A, B, C and D, which comprise 15%, 34%, 44% and 7% of the population, respectively. Group A consumes 48% of all the drugs sold in Brazil; group B consumes 36%; and group C consumes 16% of drugs. These figures do not make it clear whether the poorest group, group D, makes use of alternatives to drugs, or whether the wealthiest have an excessive reliance on medicines. However, they do demonstrate a clear imbalance in consumption patterns.

PART 2: NATIONAL POLICIES AND INSTITUTIONS

National STD/AIDS Drug Program

Alexandre Grangeiro, the ex-Director of the Brazil Ministry of Health's STD/AIDS Program has said that:

"The most important things we can teach are: how to work without hypocrisy to combat AIDS; that it is not the function of a governmental health agency to pass moral judgment on sick people; to wage the fight among the segments of the population most affected and to respect their rights; to include everyone in health services; and to have a clear policy of prevention and care."

Brazil's Law 9.313/96 guarantees every patient free access to all medicines required for treatment. The country's national strategy for the treatment of people with HIV/AIDS has received international attention, and in some instances, has been held up as a model program for developing countries. Ten years ago, Brazil had more people living with AIDS than any other country. According to government reports, its AIDS treatment and prevention campaign has resulted in a halving of the number of AIDS deaths per year and the provision of antiretroviral drugs (ARVs) to 154,000 Brazilians¹⁸. Since 1996, the AIDS incidence rate has increased from 14.6 up to 18.2 cases per 100.000¹⁹. The adult HIV prevalence is 0.6%¹⁶. There has also been a substantial reduction in hospital admissions and treatment costs associated with opportunistic infections, as well as improvements in the notification system and in epidemiological surveillance.

Twenty years ago, the Brazilian Government and the World Bank signed a loan agreement, known as AIDS I, for \$160 million for the period 1994-1998, with the aim of reducing the incidence and transmission of HIV/AIDS and strengthening public and private institutions to combat STDs/AIDS. In 1998, Brazil signed its second loan agreement with the World Bank for US\$135 million until 2002 for the prevention, diagnosis, and treatment of HIV/AIDS and for institutional strengthening. This represents the largest single AIDS project in the world ever financed by the World Bank, and was a major impetus for Brazil's efforts to address HIV/AIDS in its population.

AIDS was first identified in Brazil in 1980, and at that time was mostly confined to the big cities of Sao Paulo and Rio de Janeiro. It later spread to North, North East and Centre West Brazil. Today there is marked heterogeneity among affected persons. In 1982, all of the reported AIDS cases were among individuals with at least eleven years of formal schooling. By contrast, in 1999-2000, 71% of the people with AIDS were either illiterate or had 8 or less years of schooling. The Brazilian Ministry of Health (MOH) reports that there were 362,364 accumulated cases of AIDS in the country in 2004, though UNAIDS estimates that there are about two times that number. The MOH estimates that there are 597,443 people living with HIV. Over the past five years, the number of AIDS cases has increased dramatically among women and among the poor. Whereas the male to female ratio was 25 to 1 in the 1990s, today it is 2 to 1.

Brazil's National STD/AIDS Program's main function is to define and implement guidelines, strategies and action priorities to guarantee that individuals affected with HIV/STD have access to quality diagnosis and treatment within the public health network. The program's main activities include distance training for health professionals within the public health network; the monitoring of individuals infected through a national network of laboratories; and the operating of a national system of quality assurance for laboratory tests to evaluate the effectiveness and precision of all tests in the public health network and blood banks. A large number of civil society groups are involved in implementing the program. Among other initiatives, an NGO unit has been established within the Ministry of Health to manage the Small-Projects Fund.

Brazil's public policies in promotion and prevention of AIDS/STDs have been conducted under three major headings: behavioral intervention directed towards high risk populations; activities focussed on citizen participation and empowerment of vulnerable social groups, with the aim of getting their full participation in the process of formulating policies; and the cross-fertilization of prevention policies and activities between different areas of government and private sector. 580 projects were carried out in partnerships between NGOs and the government between 1999 and 2000, with 81 priority projects with community organizations targeting specific populations during the same period. In the meantime, 141 testing and counseling centers were set up throughout the country to offer free and confidential serological diagnosis. A major communication campaign was also carried out targeting high risk groups, such as health professionals, truck drivers and women, and occasions such as Carnival were used as opportunities to spread the message of prevention.

In 1988, Brazil began to dispense medicines against opportunistic infections. In 1991, the dissemination of the ARV Zidovudine began. The Government of Brazil committed itself to widespread dispensing of ARVs through the public health system in 1996, when it signed a law establishing free distribution. In fact, the most well-known part of the program is its free and universal access to ARVs through the public health network, SUS. This program began in the early 1990s with the distribution of AZT capsules, and was expanded and consolidated under Congressional Bill 9313 of 13 November 1996 that guarantees every patient the access, free of direct costs, to all the medication required for his or her treatment, including protease inhibitors and reverse transcriptase inhibitors, following treatment criteria and guidelines set out by the Ministry of Health. In 2001, the Ministry of Health created a list of ARVs including 12 drugs in 27 formulations. For 2005 the list will be comprised of 17 ARVs in 35 formulations²⁰. The Federal Government is responsible for ARV drugs, but procurement and distribution of drugs for treating opportunistic infections is decentralized to states and municipalities.

Price Negotiations on ARVs

In 1999, the President of the Republic passed Decree No. 3,201, of 1999, which establishes rules for the *ex officio* grant of compulsory licenses in cases of national emergency or public interest.

This Decree was updated by the Decree # 4.830/2.003²¹. However, the government has never resorted to the use of compulsory licenses, and no patent has been violated in the manufacture of generics because none of its copied drugs were under patent when Brazil's new patent law went into effect in 1997. Some have argued that the threat of compulsory licensing has been an important negotiating tool, allowing Brazil to bargain for price reductions of up to 70% with some multinational pharmaceutical companies.

In that regard, the government appointed a negotiating committee of experts, prepared a detailed study on the price of medicines, and estimated the impact on budget and cost to state-owned companies to produce the needed medicines before approaching multinational companies to bargain for price reductions. In 2001, the Ministry of Health concluded a deal with Merck to reduce the prices of 3 ARVs, Indinavir (by 64%), Lopinavir (45%) and Efavirenz (59%). Indinavir was already being produced in national laboratories, which set the benchmark for the price reduction obtained. This paved the way for negotiations with Roche regarding its patented ARV, Nelfinavir, used by nearly a quarter of patients supported by the Program. The Government prepared to issue a compulsory license in the event of failed negotiations, and Far-Manguinhos (a public laboratory that produces medicines) continued tests to evaluate the cost of local production. Far-Manguinhos achieved production at 60% of cost, which is ultimately the discounted rate that was agreed to after extensive negotiations. Ultimately, price reductions were possible in these instances thanks to the visibility of the AIDS problem, public demand, political support for the program, and national laboratories' technical capacity to produce generic copies. In 2003, Brazil negotiated with Merck, Abbott, Bristol-Myers Squibb, Gilead and Roche for a 68% price reduction. From 1996 to 2003, the average reduction in the prices of imported medicines was 47%.

As a result, the total expenditure on ARVs today is less than it was four years ago despite substantial growth in utilization. Early in 2004, the National STD/AIDS Program announced that it had received the largest price reductions on ARVs in five years, for a saving of US\$107 million that would allow 20,000 new patients to obtain treatment that year. However, by November 2004, Brazil announced that it has plans to manufacture copies of between three and five unidentified drugs, without the consent of their patent owners. The head of the national HIV/AIDS Program, Pedro Chequer, was quoted:

"After technical analysis of the sustainability of universal access to medication in this country, we determined that we have to move to a situation of self sufficiency through compulsory licensing".

Domestic Production of ARVs

Emphasis on the domestic production of ARVs started in 1993 with the production of AZT by a private firm. The following year, production in the public sector began at LAFEPE (Laboratorio do Estado de Pernambuco). By 1999, nearly half of all ARVs used in Brazil were acquired by the Government from domestic firms, the vast majority of them state-run. By 2001, this figure rose to 63%, and by the end of that year Brazil was producing 7 of the ARVs used to treat AIDS patients. Some drugs produced domestically were purchased from multinational corporations that lowered their prices and won governmental bids. Public laboratories in Brazil manufacturing ARVs include Far-Manguinhos/FIOCRUZ/Ministry of Health, Fundação para Remédio Popular/SP, Laboratório Farmacêutico do Estado de Pernambuco, Fundação Ezequiel Dias/MG and Indústria Química do Estado de Goiás.

In 2003, while three ARVs distributed by the Ministry of Health remained under patent protection, 63% of the \$573 million annual budget for AIDS treatment was used to import 3 of the drugs used in treatments (Lopinavir, Efavirenz and Nelfinavir). Today, the Ministry of Health is responsible for supplying 17 ARVs, and state governments are responsible for providing medicines to treat HIV-associated opportunistic infections. Brazil still imports a substantial proportion of its HIV/AIDS medications, and so, despite clear advances with regard to its domestic industry, Brazil is not yet self-sufficient in supplying ARV drugs to meet local demand.

Brazil has signed technical cooperation agreements with Latin American and Portuguese-speaking African countries, and others have also shown interest. In addition to supplying its domestic population, the Brazilian Government reports that it provides HIV/AIDS medicines to at least 100 patients in each of the following countries: Bolivia; Colombia; El Salvador; Paraguay; Dominican Republic; Burkina Faso; Mozambique; Namibia; Burundi; Saint Thomas and Prince; Angola and Cape Verde²². Médecins Sans Frontière (MSF), in 2001, signed agreements with the Brazilian Ministry of Health and with FIOCRUZ, establishing a cooperative arrangement involving technical collaboration on the response to HIV/AIDS. The agreement also allows MSF to purchase ARVs produced by Far-Manguinhos. Money paid by MSF goes directly into research and development for AIDS and neglected diseases.

Public Health Research & Development

Scientific research capacity is well-developed in Brazil, where 25% of the population has finished high school, and 6% have a university degree. In 2001, Brazil spent an estimated US \$ 212 million on health research. However, in 2003, President Lula's new government announced plans to double the amount of research spending in four years. Half of health research in Brazil involves groups affiliated with health sciences; one quarter is linked to biological sciences; and one quarter to other areas. The total number of researchers is about 15,000, the largest technological/scientific component in a single major field of knowledge in Brazil.

1998 saw a considerable tightening of spending on science and technology. The budget of the National Council for Scientific and Technological Development (CNPq), which oversees ten scientific institutes, experienced a 25% cut in its funding. By contrast, São Paulo, one of the richest states in the country, remained afloat, largely due to being subsidized by the 1% of state tax receipts it provides to the Foundation for Support and Research for the State of São Paulo (FAPESP). Recently, the President highlighted the good results of the CNPq in 2004 and reaffirmed the Scientific and Technological Development as a priority in his government²³. According to the National Congress amendments approved, for 2005, the estimated budget for the CNPq increased by about 10% (US\$ 28.73 million). As informed by CNPq, at the moment, they are responsible for monitoring eleven requisitions of patents in Brazil and abroad, for active ingredients for medicines of pharmaceutical substances for human and veterinarian use.

The Brazilian Government is working towards a New National Policy for Science, Technology and Innovation in Health to improve coordination between the principal funding agencies for health research, namely the Ministry of Science and Technology, and the Ministry of Health. Approximately 80% of Brazil's research groups are located in the South and South-east regions of the country, whereas the North-East region accounts for 14.5% and the North for 2.7% of total. In 2000, 80% of groups studying epidemiology in Brazil were located in the South and South-East, despite the fact that the Northern region suffers from large-scale epidemics. Furthermore, few inter-regional research networks exist. This year, about 600 delegates from health, science and technology met at the 2nd National Conference on Science, Technology and Innovation in Health, opened by the Executive Secretary of the Ministry of Health. The purpose of this large-scale meeting was to consider how to strengthen the link between scientific research and activities to benefit public health in Brazil. The Government plans to establish a body linked to the Ministry of Health to administer resources and scientific research activities in this sector. Indicators of capacity include recent evidence that articles by Brazilian researchers in international journals are increasing, accounting today for 1.3% of the total number of papers published worldwide, and the fact that Brazilians filed 98 patents with the USPTO in 2000 and 130 in 2003.

Regulation of Health Products

Brazil's Sanitary Surveillance Agency (ANVISA) was created in 1999, along the lines of the FDA, "to protect and promote population's health, ensuring the health safety of products and services, participating in the construction of the access to them". It is part of the Ministry of Health, but has administrative and financial autonomy, through taxes and other mechanisms that assure its self-sufficiency.

Pharmaceutical products, both locally-produced and imported, must be registered with ANVISA. Since 2001, Article 229-C of Law 10196 has charged that the "grant of patents to pharmaceutical products and processes [be] subjected to prior approval by ANVISA". ANVISA itself states that its role is, among others, to provide "technical support in granting of patents by the National Institute of Industrial Property" (www.anvisa.org).

ANVISA oversees reference medicines, similar and generic drugs, medical equipment, cosmetics and hospital services, and has responsibility for authorizing products on the market, as well as licensing manufacturers. User fees for ANVISA have grown substantially in recent years, so that they are ninety times higher today than five years ago. Some reports claim that, at least up until 2000, drug regulation was an area of weakness for Brazil, partly because of budget constraints and insufficient technology. Between 1997 and 1998 the Ministry of Health received 172 reports of counterfeit drugs²⁴. With the creation of ANVISA, the regulatory capacity increased and from 1999 to 2003, there were only seven confirmed cases of counterfeit drugs. Regarding substandard drugs, 2003 saw 72 drugs apprehended and destroyed and 39 were withdrawn²⁵. Technically, there is a 90 day review period for drug application registration, but processing often takes 8 to 12 months. AIDS drugs are an exception, in that registration normally takes less than one month.

In 1999, Brazil passed legislation which dealt with the licensing and registration of generic medicines. Supplementary measures provided technical standards and norms, such as bioequivalence and bioavailability standards, that are now applied by ANVISA. Generic drug approvals started to issue in 2000, and by December 2004, 1377 approvals were issued for 284 active ingredients in 5,960 dosage forms²⁶.

It should be noted that there are state-owned pharmaceutical manufacturing facilities. In 2003, the official laboratories produced 5,110,904,498 units of medicines, destined mainly to meet the needs of the Unified Health System (SUS), of which 57% of the laboratories having the Ministry of Health as their main client, 29% of them having the State Health Secretariats as their main client and 14% for the Township Health Secretariat.

The Interministerial Group of Intellectual Property (GIPI)

The Interministerial Group of Intellectual Property (GIPI) has its origins in a Brazilian coordination committee for the Uruguay Round negotiation on intellectual property. In 1995, the Chamber of Foreign Trade (CAMEX), despite the conclusion of the Uruguay Round, recognized the need to maintain that Government working group, which nowadays deals with all fields of intellectual property rights.

Comment [i2]: GIPI fez o seguinte Comentário:
Todo item deve ser suprimido, por não ser pertinente e por faltar clareza quanto à correlação do tema biodiversidade com os propósitos da Comissão da OMS. Não está clara a intenção dos autores ao mencionar exportações brasileiras das commodities.

Its participation covers the elaboration, analysis and/or monitoring of national intellectual property legislation, assistance to the preparation of the Brazilian position concerning international debates and/or negotiations involving intellectual property issues (Commission of Intellectual Property Rights of the Subgroup 7 "Industry" of Mercosul, Free Trade Area of America, European Union and Mercosul Association, World Intellectual Property Organization, Council for TRIPS of the World Trade Organization, etc.), attendance to solve demands from inside and outside the Government, and improvement of the Brazilian intellectual property culture.

As established by a Presidential Decree of 2001, the Group is a part of the CAMEX and is composed by the Ministry of Agriculture, Livestock and Food Supply, Ministry of Science and Technology, Ministry of Culture, Ministry of Development, Industry and Foreign Trade, Ministry of Foreign Relations, and Ministry of Health. Several others government bodies also participate in their meetings, mainly through its thematic subgroups, like the National Institute of Intellectual Property Rights (INPI) or the Brazilian Sanitary Surveillance Agency (ANVISA). In fact, more than fifteen other government bodies have already participated in their government meetings.

The participation of the government bodies having a competence and/or a direct interest on the subject has been allowing for a holistic evaluation of the agenda and its themes, making it easier to assist the development and harmonization of the Government position concerning intellectual property issues towards the improvement of Brazilian intellectual property policy.

In the field of patents and public health, for instance, GIPI was responsible for the concretization of the Decree 3,201, of 1999, and its modifications provided by the Decree 4,830, of 2003, which establishes rules concerning the *ex officio* concession of compulsory licenses in cases of national emergency and public interest.

Research-Based Pharmaceutical Companies

Brazil is Latin America's largest market, comprising 67% of MERCOSUR (Argentina, Brazil, Paraguay, and Uruguay). Recognizing its potential for growth, the research-based pharmaceutical industry has targeted Brazil as one of its "strategic markets". Brazil is the world's 11th largest pharmaceutical market in terms of sales, and is its 6th largest in volume. In 2003 there was 450 drug manufacturers authorized in Brazil¹¹.

ABIQUIF is the Brazilian Association of Pharmedical Industry. The Brazilian Federation of the Pharmaceutical Industry (FEBRAFARMA) was founded officially on June 14th, 2002 and gathers 15 entities representing the sector, which in turn represents 252 drug manufacturers, including ALANAC, the association for the national pharmaceutical laboratories. From the laboratories represented by FEBRAFARMA, 48 (19%) have foreign investment and 204 (81%) national investment. The multinational companies account for 70% of sales in the local market, excluding the purchases made by the Government²⁷.

Generic Drug Sector

Brazil's generic production is heavily dependent on active ingredients purchased from India, and in 2001 85% of raw materials used in the production of generic drugs in Brazil were imported. For instance, while the industry group PhRMA has acknowledged that the success of Brazil's national AIDS treatment program is due to political will, relatively good public health infrastructure, testing, financing, chiefly from the World Bank, the group avows that Brazilian laboratories are not in a position to supply their market or the wider South American market reliably or on a large scale across the full range of therapeutic categories. Nonetheless, eighty percent of generic medicines marketed in Brazil are locally produced by Brazilian companies (finished dosage form), accounting for 74.6% of total sales value. Indian companies account for 10.3% of the generics market, followed by Germans, Swiss, Americans, and Canadians. The market share of generic medicines in Brazil is about 10% of the total medicines market in number of units sold, and about 5% of its value. This is due, in part, to the fact that generic medicines must, according to "informal" government policy, be nearly 40% cheaper than the brand name reference products. These medicines are manufactured by 56 companies, of which 27 are national. The industry expects to reach 30% of market share of units by 2007. Pro-Genéricos, Brazil's generic medicines industry association, has data buttressing the view that implementation of generic-related policy has led to a strengthening of the local pharmaceutical industry. They have calculated that the generics industry has invested nearly R\$1 billion in the construction and modernization of the country's drug plants.

Until the 1999 Generics Law approval, all products besides the reference were "similar medicines". The "similar" were registered solely on the basis of similarity, and did not have to provide evidence of inter-changeability, which requires comparative testing for bioequivalence. In 2003, ANVISA mandated that similar medicines would also require testing for bioequivalence against a reference drug.

The Ministry of Health has proposed lists of priority products, based on WHO's model list as well as the country's own essential medicines list and market considerations, for which it encourages the creation of generic copies. There have been reports of positive reactions from among generics manufacturers to this policy.

Biotech Sector

Brazil's biotechnology sector has also shown rapid expansion and modernization. Within the biotech sector, there is an annual turnover of US\$ 4 billion or 1.5% of GDP. It is a young industry in Brazil, where 50% of biotech companies are start-ups or have been around less than 7 years, and employs about 30,000 people. Eighty percent of companies and universities are based in the South Eastern region. Brazil is home to world-class biotech research centers, most notably FIOCRUZ and Instituto Butantan. It is also considered to be at the forefront of genome research, alongside the United States and the United Kingdom. Brazil has been credited with successfully applying a network-based research strategy in the context of genomics, which has resulted in world-class results. For instance, in 2000 Brazilian scientists sequenced *X. fastidiosa*, a bacterium that devastates plantations by infecting citrus crops.

Besides pharmaceuticals, Brazil has developed recognized expertise in the production of vaccines, though vaccines produced in the country are mostly used domestically, they are produced using foreign technology. In some cases they are exported to Portuguese speaking countries in Africa, and some countries in Latin America under technical cooperation. Brazil has shown indications of working towards production of vaccines for commercial purposes, particularly for the MERCOSUR market. ABIFINA is the Brazilian association of chemical, specialty and biotech industries.

Non-Governmental Organizations

NGOs, such as Médecins Sans Frontières (MSF), are very active in the health sector in Brazil, and have played an important role in influencing policymaking. They have successfully raised the profile of a range of diseases, most notably HIV/AIDS, and brought the spotlight onto trade and politics, forcing a health-sensitive perspective. Brazil's national program to control HIV/AIDS and other sexually transmitted diseases, described above, highlights how NGOs and community groups have not only been influential in the process of policymaking, but highly engaged in implementation of policy.

The Brazilian Network for People's Integration (REBRIP)'s Intellectual Property Working Group (GTPI) has a very active role. REBRIP gathers Brazilian civil society organizations to follow-up and monitor the commercial agreements where the Brazilian Government is involved, with a view to evaluating and minimizing its impact on the population's day-to-day lives. One of the relevant subjects within the context of discussion over free trade refers to intellectual property, the reason why REBRIP created a working group to address civil society's claims in respect of this issue (GTPI). GTPI's lines of work are as follows: follow-up on international negotiations on intellectual property where Brazil is included; further the intellectual property debate before the legislative power; alter the Brazilian patent system, with a view to promoting access to drugs; mobilize public opinion regarding the social impact of intellectual property commercial agreements; and strengthening ties with civil society organizations of Latin-America and African Portuguese-speaking countries.

Among the GTPI members, are AIDS Support and Prevention Group of São Paulo State, Life Incentive Group (GIV), Consumer Protection Institute (IDEC), International Commerce Law and Development Institute (IDCID). The GTPI is coordinated by ABIA relies on the collaboration of the following organizations: Action Aid, MSF and OXFAM International.

REFERENCES

- Smith CS. A model for the world: How Brazil's citizens and government officials alike avoided an AIDS catastrophe and ensured the health of HIVers. *A&U*, Sept 2004. www.aumag.org/features/BrazilSeptember04.html
- Lima AA. Brazilian chemist leads battle against HIV/AIDS. *Women's e-news*, 15 June 2004. www.womensenews.org/article.cfm/dyn/aid/615/context/cover
- Cardoso M. Brazilian Amazon gets help from science. *Brazzil*, Aug 2004. <http://www.brazzil.com/2004/html/articles/aug04/p101aug04.htm>
- Guimarães R. Towards a policy for science, technology and innovation in health. *Cad. Saúde Pública*, Nov-Dec 2002. 18(6):1496-7.
- Coimbra, C.E.A. Jr. Challenges for scientific output and communications in health in Brazil. *Cad. Saúde Pública*, Jan-Feb 2003. 19(1):4-5.
- Vieira CL. Brazil's budget crunch crushes science. *Science*, Nov 1998. 282(5393):1403-4.
- Pennisi E. Brazil wants cut of its biological bountry. *Science*, 6 March 1998. 279(5356):1445.
- Simpson AJG, AA Camargo, JA Ferro, J Parra, AT Vasconcelos. Coordinated, network-based research as a strategic component of science in Brazil.
- De Castro Moreira, I. Brazilian science at a crossroads. *Science*, 11 July 2003. 301:141.
- Guimarães R. Financing and priority setting in health research in Brazil. www.globalforumhealth.org/forum7/CDRomForum7/wednesday/Plenary4aGuimaraesFull.doc
- The AIDS epidemic in Brazil. www.aids.gov.br/durban/10cap1_ing.pdf
- National AIDS drug policy. Ministry of Health of Brazil, June 2001
- HIV/AIDS control: The Brazilian experience. Ministry of Health, Secretariat of Health Policies, National Programme for STD/AIDS.
- Timoteo da Costa M. Brazil's pioneering AIDS programme. *BBC News*, 14 July 2003.
- Brazil Aids programme copied abroad. *BBC News*, 14 Sept 2001.
- Brazil's national STD/AIDS programme announces largest drug price reduction deals in five years. *Kaiser Daily HIV/AIDS Report*, 20 Jan 2004.

- Biotechnology and pharmaceuticals market in Brazil. *UK Trade & Investment*, 2003.
www.trade.uktradeinvest.gov.uk/biotechnology/brazil/profile/overview.shtml
- Cohen JC. Public policies in the pharmaceutical sector: a case study of Brazil. The World Bank LCSHD Paper Series No.54.
- Mossinghoff G. Case study: Brazil's pharmaceutical industry. Introduction to Intellectual property rights. Usinfo.state.gov
- Clendenning A. Brazil's drug copying industry. *CBSNews.com*, 25 Sept 2003.
- Bussey J. Brazil rises to powerful role in trade diplomacy. *The Miami Herald*, 23 Nov 2003.
- Osava M. India-Brazil: cementing the South-South alliance. *Global Policy Forum*, 31 Jan 2004. www.globalpolicy.org/globaliz/econ/2004/0131indiabrazil.htm
- US-Brazil war of words over pharmaceuticals and intellectual property. *ICTSD Bridges Weekly Trade New Digest*, 8 May 2001. 17(5):
www.ictsd.org/html/weekly/08-05-01/story5.htm
- Letter from Nicolas de Torrente (MSF) to the Chair of the Committee of Government Representatives on the Participation of Civil Society, 1 May 2002.
- Galvao J. Access to antiretroviral drugs in Brazil. *Lancet*, 7 Dec 2002. 360:1862-5.
- Brazil - Myths and Facts. PhRMA, Health care in the developing world.
<http://world.phrma.org/brazil.myths.facts.html>
- Bermudez J, R Epszstejn, MA Oliveira, L Hasenclever. Access to drugs, the WTO TRIPS Agreement, and patent protection in Brazil: Trenes, perspectives, and recommendations to help find our way. *MSF/DND Working Group*, 20 Feb 2002.
- Shanker D. Brazil, the pharmaceutical industry and the WTO. *Journal of World Intellectual Property*, Jan 2002. 5(1):53-104. (Abstract : available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=272208)
- Harrington M. Brazil: what went right? The Global challenge of access to treatment and the issue of compulsory licensing. Treatment Action Gropu. 10th National Meeting of People Living with HIV and AIDS, 3 Nov 2000. Rio de Janeiro, Brazil.
- Zarilli S. "The case of Brazil", in Trade in health services: global, regional and country perspectives (Drager N, Vieira C, eds.). Pan American Health Organization / World Health Organization, 2002.

De Oliveira W. Brazil eases restrictions on biodiversity researchers. *Scidevnet*, 12 Nov 2003.

Oliveira J. Overview of drugs and pharmaceutical market - Brazil. Industry Canada, 27 July 2001. <http://strategis.ic.gc.ca/epic/internet/inimr-ri.nsf/fr/gr-73135f.html>

"Chapter 1: Brazil biodiversity". First national report for the Convention on Biological Diversity - Brazil. Ministry of the Environment.

Weissman R. "Free trade" and medicines in the Americas. vol 6, no 13. *Essential Action*, April 2001.

Bermudez JAZ, MA Oliveira (eds). Intellectual property in the context of the WTO TRIPS Agreement: challenges for public health. Escola Nacional de Saude Publica Sergio Arouca. Rio de Janeiro, September 2004.

Additional References

¹ BRASIL. Instituto Brasileiro de Geografia e Estatística. **Área Territorial Oficial**. <http://www.ibge.gov.br/>. Access in: 18/01/2005.

²REDE INTERAGENCIAL DE INFORMAÇÕES PARA A SAÚDE (RIPSA). IdB 2004 Brasil: indicadores e dados básicos para a saúde. Brasília: OPAS/OMS, 2004. Available at: <http://www.datasus.gov.br/cgi/idb2004/matriz.htm>

³ Instituto de Pesquisa Econômica Aplicada (IPEA). **Ipeadata**: dados macroeconômicos e regionais. Available at: <http://www.ipeadata.gov.br> Access: 18/01/2005.

⁴ Organização Pan-Americana da Saúde/Organização Mundial da Saúde. **Perfil da Reforma do Sistema de Saúde no Brasil**: Texto complementar ao Perfil 2002, com atualização de informações. Brasília: OPAS/OMS, 2005. Available at: http://www.opas.org.br/servico/paginas/sala/exibe_titulos.cfm?CodSubTema=70 Access: 18/01/05.

⁵ ORGANIZAÇÃO PAN-AMERICANA DA SAÚDE/ORGANIZAÇÃO MUNDIAL DA SAÚDE. O Perfil do Sistema de Serviços de Saúde – Brasil. 2 ed. Brasília: OPAS/OMS, 2001. Available at: http://www.opas.org.br/servico/paginas/sala/exibe_titulos.cfm?CodSubTema=70 Access: 18/01/05.

⁶ BRASIL. Agência Nacional de Saúde suplementar. **Caderno de Informações em Saúde Suplementar**: Relatório Nacional http://www.ans.gov.br/portal/site/perfil_gestores/cadernogestores/200312_nac.pdf [competência: dezembro/2003]. Access: 19/01/2005.

⁷ORGANIZACIÓN PANAMERICANA DE LA SALUD/ORGANIZACIÓN MUNDIAL DE LA SALUD. **Situación de Salud en las Américas**: indicadores básicos. Washington DC: OPS/OMS, 2004. Available at: <http://www.paho.org/Spanish/SHA/coredata/tabulator/newTabulator.htm>

⁸ BRASIL. Ministério da Saúde. **Política Nacional de Medicamentos**. Brasil: Ministério da Saúde; 1998. (Série C. Projetos, Programas e Relatórios, n. 25). Disponível em: <<http://www.opas.org.br/medicamentos/docs/pnm.pdf>>. Acesso em: 28 maio 2004.

⁹ BRASIL. Conselho Nacional de Saúde. Resolução n. 338, de 06 de maio de 2004. Aprova a Política Nacional de Assistência Farmacêutica. **Diário Oficial [da] República Federativa do Brasil**, Poder Executivo, Brasília, DF, 20 maio 2004. Seção 1. disponível em: <http://www.opas.org.br/medicamentos/docs/pnaf.pdf>

¹⁰ BRASIL. Ministério da Saúde. **Relação Nacional de Medicamentos Essenciais: RENAME**. 3ed. Brasília, 2002. (Série B. Textos Básicos de Saúde). Disponível em: <<http://www.opas.org.br/medicamentos/docs/renome02.pdf>> Acesso em: 13 set 2004.

¹¹OMS. Cuestionario sobre estructuras y procesos de la situación farmacéutica nacional: Brasil. Fecha: 09/06/2003.

¹² Brasil. Ministério da Saúde. **Farmácia Popular do Brasil**. Available at: <http://dtr2002.saude.gov.br/farmaciapopular/> Access: 19/01/0225.

¹³ CONFERÊNCIA NACIONAL DE MEDICAMENTOS E ASSISTÊNCIA FARMACÊUTICA, 2003, Brasília. **Relatório final preliminar**. Brasília: Ministério da Saúde; 2003. 67p.

¹⁴ WTO – WT/DS199/4 – G/L/454 – IP/D/23/Add.1 – 19 July 2001

¹⁵ FEDERAÇÃO BRASILEIRA DA INDÚSTRIA FARMACÊUTICA. **Tabela de indicadores selecionados**. Boletim n. 048-04. Available at: <http://www.febrafarma.org.br/areas/economia/economia.asp?area=tc> Access: 19/01/2005.

¹⁶ BRASIL. **Agência Nacional de Vigilância Sanitária**. www.anvisa.gov.br

¹⁷ BRASIL. Lei 10.742, de 06 de outubro de 2003. Define normas de regulação para o setor farmacêutico, cria a Câmara de Regulação do Mercado de Medicamentos - CMED e altera a Lei no 6.360, de 23 de setembro de 1976, e dá outras providências. **Diário Oficial [da] República Federativa do Brasil**, Poder Executivo, Brasília, DF, 7 out 2003. Seção 1., p. 1.

¹⁸ UNAIDS/PAHO/TREAT3X5. **Fact Sheets on HIV/AIDS Care and treatment**. October 2004.

¹⁹ BRASIL. Ministério da Saúde. **Boletim Epidemiológico AIDST**. <http://www.aids.gov.br/final/dados/BOLETIM2.pdf>, consultado 19/01/05

²⁰ BRASIL. Ministério da Saúde. **Programa Nacional DST/AIDS**. Available at: www.aids.gov.br access: 19/01/05

²¹ Bermudez Jorge, Maria Auxiliadora Oliveira e Gabriela Costa Chaves. O Acordo TRIPS da OMC e os desafios para a Saúde Pública. Em: Bermudez Jorge Zepeda; Oliveira, Maria Auxiliadora e Esher, Ângela. Organizadores. **Acesso a Medicamentos: Derecho fundamental, papel del estado**. Rio de Janeiro: ENSP;2004

²² BRASIL. Ministério da Saúde. Programa Nacional DST/AIDS. **Assessoria de Cooperação Externa**. Available at: www.aids.gov.br Access: 19/01/05

²³ BRASIL. Conselho Nacional de Desenvolvimento Científico e Tecnológico (CNPq). **Lula ressalta trabalho do CNPq e reafirma prioridade para C&T**. Available at: <http://www.cnpq.br/noticias/2005/110105.htm>. access: 20/01/2005.

²⁴ OFICINA NACIONAL “PREVENÇÃO E COMBATE À FALSIFICAÇÃO E FRAUDE DE MEDICAMENTOS: UMA RESPONSABILIDADE COMPARTILHADA”. Brasília, 09 e 10/03/2004. **Termo de Referência**. Brasília: OPAS/OMS; ANVISA; 2004. Available at: http://www.opas.org.br/medicamentos/docs/HSE_FAL.pdf , access: 18/01/2005

²⁵ FORUM NACIONAL DE PREVENÇÃO E COMBATE À FALSIFICAÇÃO DE MEDICAMENTOS: uma responsabilidade compartilhada. Brasília, 06 de julho de 2004. **Termo de Referência**. Brasília: OPAS/OMS; ANVISA; 2004. Available at: http://www.opas.org.br/medicamentos/docs/HSE_TER_FOR_0704.pdf, access: 18/01/2005

²⁶ BRASIL. Agência nacional de Vigilância sanitária. **Medicamentos genéricos: Visão Geral**. <http://www.anvisa.gov.br/hotsite/genericos/estatistica/geral.pdf>, consultado em 19/01/05

²⁷ FEBRAFARMA. **Quem somos**. Available at: http://www.febrfarm.org.br/areas/febrfarm/quem_somos.asp, access: 18/01/2005.