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Public Policies in the Pharmaceutical Sector: A Case Study of Brazil

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Currency Equivalents
(Exchange Rate Effective May 7, 1999)

Currency Unit =Real (R$)
R$ 1.70 = US$ 1.00

Abbreviations and acronyms

ABIFARMA	Pharmaceutical Industry Association of Brazil
ANVS	National Agency of Sanitary Surveillance
CEME	Central Medicines
CENABAST	Chilean Central Drug Purchasing Agency
COFINS	Social Security Tax
ECDS	Eastern Caribbean Drug Service
FIOCRUZ	National School of Public Health
FURP	Sao Paulo Public Drug Manufacturer
GDP	Gross Domestic Product
GMP	Good Manufacturing Practices
GPIUM	The Group to Prevent the Inappropriate Use of Medicines
HNP	Health, Nutrition and Population
LCR	Latin America and the Caribbean Region
PAB	Per Capita Transfer to Primary Care
PSF	Family Health Programme
MERCOSUR	Southern Common Market
R & D	Research and development
SUS	Unified Health Care System
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UNIDO	United Nations Industrial Development Organisation
WHO	World Health Organisation
WTO	World Trade Organisation

Summary

This discussion paper provides an overview of pharmaceutical sector trends in Brazil. It focuses on three key areas in the pharmaceutical sector: supply and distribution, financing, and institutional capacity. The paper concludes that focusing on: (a) strengthening the enforcement of drug regulations and (b) building public procurement capacity could improve the availability of cost-effective and appropriate quality drug supplies for the poorest members of the population. Public-private partnerships in pharmaceuticals could contribute to greater effectiveness in both sectors. This paper was based on consultations with stakeholders in Brazil and Washington from September 1998 - March 1999, as well as on policy documents and legislation relevant to the pharmaceutical sector.

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Introduction

1.1. Context and Health Institutions

1. Brazil is a middle-income country[1] with a population of 166 million in 1998. Brazil has a persistent poverty problem, which the Bank attributes to years of poor economic performance. Brazil also has one of the most skewed income distributions in the world. The highest 10 percent of the income distribution in Brazil receives almost half of the income, 47.9 percent, compared to 42 percent in Mexico, 37.4 in the Russian Federation, 28.5 percent in the United States, and 23.8 percent in Canada.[2]

2. Pursuant to Article 196 of the 1988 Constitution, health services (including access to basic medicines) are considered a constitutional right in Brazil. Universal access is the central principle of the system. As the Constitution expresses: "(h)ealth 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 delivery of public health care services is formally shared equally by the different levels of government: federal, state, and municipal. The government health financing system (Sistema Unica da Saude (SUS)) is organised to reflect this. In practice, the delivery of health services is increasingly being decentralised to the state and municipal levels.

3. In 1999, the federal health budget represented 3.3% of the GDP, or R$ 14.2 billion. Health revenues are derived from taxes for social security, corporate taxes, financial transactions, and others. All of these are deposited in a social security account, which includes financing for pensions, health services, and social assistance.[3] The federal government provides the majority of the financial resources for the public health expenditure in Brazil – about 71%. States contribute about 15% and municipalities the remainder – 14%.[4] States and municipalities also have the right to specific tax and expenditure functions, and are entitled to take over full management of basic health care for their respective health systems. They also can choose to "opt-out" of managing health services, and let the federal government take responsibility for their provision.

4. Although SUS is responsible for financing health care for all of the population, its clients are mainly the 123 million Brazilians (74%) who do not have private insurance. (World Bank, Brazil Health Sector Strategy, 1999). The SUS contracts out a large majority of inpatient care and outpatient care to a network of private and philanthropic hospitals, clinics and other facilities. The public sector, in fact, only manages and owns 31% of the hospital beds SUS supports.

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[1] GNP per capita of Brazil is US$ 4,570 per capita (World Development Report 2000).
[2] World Bank Development Indicators, 1999.
[3] The Brazil Health System: A Sector Impact Study, Washington, World Bank, Operations Evaluation Department.
[4] World Bank, Brazil Country Management Unit, Brazil Health Sector Strategy, Draft,1999.

5. Joint management commissions have been established to facilitate the coordination activities among the various levels of government. For the health sector, there is a tripartite joint management commission comprised of equal representation from the Ministry of Health, the National Council of State Secretaries of Health, and the National Council of Municipal Secretaries of Health. The members of the bipartite joint commissions are the state secretariat of health and the municipal representatives of health.[5] Health councils, permanent bodies at each level of government, are also in place. They are charged with overseeing the implementation of health programmes and have user representation (e.g. labour unions, patient groups) as well as representation from the health sector. Despite these institutional arrangements, it is not always clear who is developing health policy.

6. Decentralisation has also been supported through the Basic Care Floor (Piso de Atencao Basico (PAB)) and the Family Health Program (Programa de Saude da Familia (PSF)). The PAB guarantees the financing of select ambulatory services for municipalities capable of managing them. The federal government transfers resources to the municipal governments on a per capita basis. This ranged between R$ 10 to R$ 18 in 1998 or about US$ 8 to US$ 15. [6] The PSF is designed to promote community care and has a strong educational component. The cornerstone of this programme is the health team, whose members include a medical doctor, nurse, nurse auxiliary, and six health agents, who monitor health indicators and provide basic health services at the local level. The state of Ceara in Northeast Brazil is considering including a pharmacist per four health teams (or one pharmacist per 20,000 persons).

1.2 Health Sector Weaknesses

7. Democratic decision making and decentralisation of core public service responsibilities have not yet produced greater equity,[7] democratisation of resource allocation, nor necessarily better quality in the provision of products and services in the health sector. A recent Bank report acknowledged that with the complexity of the Brazilian health system, it is hard to tell what incentives are being offered to different actors and what distortions they face.[8]

8. The World Bank Operations Evaluation Department (OED) conducted a study of the Brazilian health sector and identified four problem areas in the health sector. They are: (1) severe under-financing of the public system resulting in regional inequalities, arbitrary rationing in facilities, and a perceived decline in quality; (2) weak incentives for cost-effectiveness and quality; (3) tension between decentralisation and the provision of the quality of care; and, (4) an over emphasis on curative services.[9] Brazil also has geographic disparities in the quality of public health services.

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[5] PAHO, Health in the Americas, Volume II, Brazil, pp. 122.
[6] Proposed Social Protection Special Sector Adjustment Loan, Report No. P7231, BR., p. 42. The US dollar equivalents are calculated at the November 1998 rate of R$ 1.19 = US$ 1.00
[7] See Kurt Weyland (1996) Democracy Without Equity: Failures of Reform in Brazil. Pittsburgh: University of Pittsburgh Press.
[8] World Bank, Brazil Social Spending in Selected States, Chapter 3, draft, Washington, 1998, pg. 44.
[9] The Brazil Health System, op.cit., p. 19.

2. World Bank Involvement in the HNP and Pharmaceutical Sectors

2.1 Background on the Bank's activities in the Brazil HNP sector

9. Brazil is one of the Bank's largest recipients of HNP financing (see Table 1 below). During fiscal years 1988-1998, Brazil was the recipient of US$ 935 million in commitments and had 5 active HNP projects. In the Latin America and Caribbean region (LCR), Brazil is the second largest recipient of HNP financing, after Mexico.

Table 1. Largest Recipients of HNP 1988-98

	$millions
India*	2777
Mexico	1215
Brazil	935
Argentina	691
China*	594
Bangladesh*	490
Indonesia	445
Russia	336
Venezuela	248
Nigeria	244
[*IDA or mainly IDA]	

	No. of Projects
India*	20
Argentina	6
Brazil	5
Mexico	4

10. Since 1983, Brazil has had four Bank health projects with direct lending for the pharmaceuticals -- The Northeast Endemic Project, Amazon Basin Malaria, AIDS I, and the Northeast Basic Health Services II. Indirect lending for pharmaceutical activities has been provided to the government through the Reforsus I project. Total commitments to the sector thus far has been about US$ 93 million.

2.2 The Bank's Activities in the Pharmaceutical Sector

11. Since the early 1980s, the Bank has supported improved pharmaceutical policies in its client countries through policy dialogue on pharmaceutical issues with governments and through its lending practices. One estimate is that the Bank commits about US$ 220 million annually for project components related to pharmaceuticals, or about 17% of new health lending.[10] Financing includes support for drug procurement, related medical supplies, computers, civil works, technical assistance, and training. In LCR from fiscal years 1983-1997, 15 health projects in the region included a pharmaceutical component. Estimated committed lending to pharmaceuticals in the region during this period was US$ 184 million.

2. 3 Rationale for Bank Activities in the Pharmaceutical Sector

12. As long as the Bank continues to invest in the health sector, it will be involved in the pharmaceutical sector because drugs are critical inputs of a health system. Pharmaceuticals can both cure and prevent diseases, and if used appropriately, can

[10] Michael Reich, Ramesh Govindaraj, and Jillian Cohen, Draft Document, World Bank Pharmaceutical Discussion Paper, January 2000.

intensify investments made in other areas of the health system.[11] Because pharmaceuticals lie at the nexus of the health and commercial sectors, pharmaceutical policies can also create tensions between the two sectors. The challenge, then, is for governments to develop pharmaceutical policies which support public health goals and the development of private industry.

13. Information asymmetry between pharmaceutical manufacturers and regulatory agencies in developing countries is also an obstacle for the effective regulation of these companies, because regulators have limited capacity to know what the true costs of production are.[12] Production costs for pharmaceuticals vary according to whether the firm does research and development, or manufacturers generic drugs. In developing countries, there are distortions between the "need" (as measured by priority health problems) and the demand (as reflected by consumption patterns) for pharmaceuticals. These distortions and inequities exist by disease, by income, by the age distribution of patients, by geographical area, and by level of care.[13]

14. Pharmaceutical budgets are often not maximized because of erratic supply, poor quality, and the irrational use of drugs. The risk of these problems have been articulated in a number of World Bank policy papers.[14] They could be minimized through efficient procurement procedures and distribution systems. [15] Good procurement practices in particular can generate savings which, ideally, can be used to purchase more basic drugs for those in need.[16]

Best Practice #1 Estimating Safety Stock. The minimum safety stock needed to avoid a stockout is the quantity of stock used on average during the average lead time from the current supplier: This means that if an order is placed as soon as the stock level falls to the safety stock level, if demand is no greater than average during the lead time, and if the supplier delivers within the average lead time, a stockout will be avoided. The most common method for estimating safety stock needs is to determine the average lead time for each item from the current supplier and the average consumption (per month or per week). If there were stockouts consumption must be adjusted to what would have been used. The formula for setting the basic safety stock (SS) level is lead time (LT) multiplied by the average consumption (Ca): SS=LT x Ca.

Source: Managing Drug Supply, 1997, Box 15.2

[11] Pharmaceuticals can improve life expectancy and reduce the need for hospitalization.
[12] Jean-Jacques Laffont and Jean Tirole. A theory of incentives in procurement and regulation. Cambridge, Mass. MIT Press. 1993.
[13] Govindaraj et al., 1999.
[14] See the World Development Report: Investing in Health (1993) and Better Health in Africa (1994).
[15] Better Health in Africa, World Bank, 1994.
[16] Based on recommendation of Helen Saxenian "Getting the Most out of Pharmaceutical Expenditure" Human Resources Development and Operations Policy Working Papers, September 1994, No 37.

Understanding the Pharmaceutical Sector in Brazil

3.1 Background on the Pharmaceutical Sector in Brazil

15. The pharmaceutical sector in Brazil is undergoing changes in the organisation, financing, and delivery of basic medications to the population. Since January 1999, states and municipalities have been responsible for the purchase and distribution of basic medications. Formerly, this was managed centrally by CEME (Central de Medicamentos), and then under the national *Farmacia Basica* programme.[17] The government has also created a new health agency – the Agencia Nacional de Vigilancia de Sanitaria (ANVS) to oversee the quality of health services in Brazil, including pharmaceuticals (See 4.7). Legislation to promote generic drugs has also recently been approved by the Congress.

16. The pharmaceutical sector in Brazil is the sixth largest in the world in terms of value and is the leading market in Latin America.[18] The research based pharmaceutical industry has targeted Brazil as one of its global "strategic markets" given its potential for growth.[19] Although Brazil has good human resources, laboratories, and institutions (e.g., FIOCRUZ), the pharmaceutical sector has many weaknesses. Two of these are insufficient quality assurance and inconsistent supplies of essential drugs in the public health system .

17. Many of the problems in Brazil's pharmaceutical sector are found in developing countries. For example, the poor spend a higher percentage of their family income on pharmaceuticals, at rates which are growing through time (see Medici below). And, although there is legislation specifying that only a pharmacist has the right to register a pharmacy, in practice, it is rare to find a pharmacist employed in a private pharmacy. Self-medication is common throughout Brazil, and can result in the development of drug resistant bacteria. Drug use does not always match health needs; many doctors feel compelled to prescribe medicines to their patients, even if there is no health need, because patients tend to associate the quality of a health professional with their willingness to prescribe drugs. Another problem is that physicians sometimes prescribe a drug, based on the purchasing power of the patient, rather than on their health need.[20]

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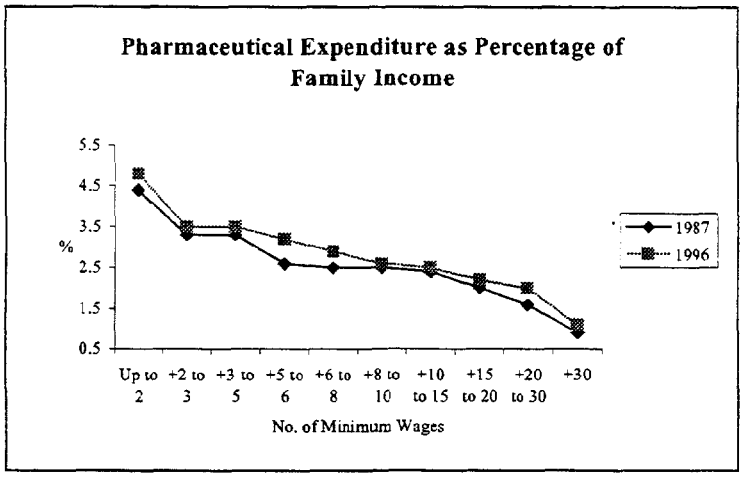
[17] States and municipalities have different levels of autonomy in terms of how well they are able to manage, plan, and deliver health care activities.

[18] At ex-manufacturing prices and including both the public and private sectors. Source: ABIFARMA, 1998.

[19] A conservative estimate is that about 10% or some 16 million persons do not have financial and\or physical access to drugs.

[20] Booz, Allen & Hamilton, The Healthcare Industry in Brazil, Sao Paulo, 8/9/98.



Source: André Cezar Medici, O SUS e a Política Hood Robin de Saúde, mimeo, Washington, 1998.[21]

18. In 1998, world sales of pharmaceuticals were estimated at US$ 302.9 billion. Although the proportion of world sales which are in developing countries tends to be small, Brazil is the exception. [22] The value of both the public and private pharmaceutical market in Brazil was estimated at US$ 10.3 billion in 1997, with international and domestic pharmaceutical companies respectively commanding about 70% and 30% of the total market. In 1996, original and licensed brands had a market share of about 58% whereas unbranded and "other" brands had about 42%.[23] The market in Brazil is fragmented; no firm commands more than 5% of the market, which is a common feature of the pharmaceutical market throughout the world.[24] The sub-markets for specific products, on the other hand, are less competitive given that companies tend to specialise in therapeutic categories.[25]

19. Latin America's 32 countries comprised only 8% of the global pharmaceutical market in 1998.[26] But it is the fastest growing regional pharmaceutical market in the world. From 1989 to 1994, the market grew by 136%. This meant that Latin America exceeded the growth of all other regions by such an extent that even its nearest competitor, Japan, expanded its sales by a considerably less 73% in the same period.[27]

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[21] Minimum salary is equivalent to about US$ 100 per month.
[22] Scrip Magazine, January 1999.
[23] Source: Richard P. Rozek and Ruth Berkowitz " The Effects of Patent Protection on the Prices of Pharmaceutical Products – Is Intellectual Property Protection Raising the Drug Bill in Developing Countries?' The Journal of World Intellectual Property, Geneva, March 1998, Volume 1. No. 2 , Annex 11.
[24] Booz, Allen & Hamilton, The Healthcare Industry in Brazil, Sao Paulo, 8/9/98.
[25] See Medici, Andre Cezar, Kaizo Iwakami Beltrao, and Francisco de Oliveira. "Pharmaceuticals Policy in Brazil," Policy Document no. 9, Sao Paulo, Brazil, Institute of Applied Economic Research – IPEA, March 1992.
[26] Scrip Magazine, January 1999, p. 30.
[27] http://www.ifc.org/PUBLICAT/FDINEWS/VOL12/VOL12.HTM#anchor578766.

Box 1. Mercosur

Mercosur is a free trade zone which encompasses Argentina, Brazil, Paraguay and Uruguay. Mercosur has a number of technical working groups in place, including one which deals with health products (including pharmaceuticals). One of the major issues which the common market is addressing is the need for harmonization of drug regulations. Brazil has 67% of the Mercosur's pharmaceutical market.[28] For more information, see the website: http://www.mercosur.com/htdocs/main.html.

3.2 Pharmaceutical Expenditures by Income Group

20. In Brazil, like most countries in the Latin America region, over 80% of drug expenses are paid for by private means; most of this is out-of-pocket spending.[29] Private health insurance is growing for the wealthiest members of the population. In 1988, 11 million persons subscribed to a health insurance scheme; it is estimated that about 45 million Brazilians presently subscribe to private health insurance schemes, which do not tend to cover pharmaceuticals. Some plans offer discounts on drugs if they are purchased at a particular pharmacy, or pharmacy chain.

21. ABIFARMA *(Associacao Brasileira da Industria Farmaceutica)* has developed a profile of the Brazilian market that offers some telling insights into the tiered nature of the pharmaceutical market, which is representative of basic economic trends in Brazil. It classifies the consumer into one of three income groups: A, B or C. Group A represents 15% of the population; its members consume about 48% of all pharmaceuticals sold. Spending per capita of Group A is R$ 205 per capita. (This consumption pattern is similar to the pattern in Spain or in the United Kingdom). Group B represents 34% of the population; its members consume about 36% of all pharmaceuticals sold. Spending per capita of Group B is R$ 68. Finally, Group C represents 51% of the population and they consume 16% of all pharmaceuticals sold. Spending per capita of Group C is R$ 20 per capita (see Table 2 below).

22. The striking difference in drug consumption among the Brazilian population demonstrates that the pharmaceutical consumption rates are closely related to income group. This poses the question of whether the government should consider reallocating its pharmaceutical resources more heavily towards lower income groups or select groups of the population, such as the elderly and children?

[28] Booz, Allen & Hamilton, "The Health Care Industry in Brazil" 8/9/98.
[29] Pharmaceuticals and Health Sector Reform in the Americas: An Economic Perspective, WHO, p.27.

Table 2. BRASILIAN PHARMACEUTICAL CONSUMER PROFILE[30]

GROUP	Salary Range (monthly basis)	Percentage of the Population	%Market Share Consumed	Per Capita Expenditure on Pharmaceuticals
A	10 minimum salaries +	15	48	R$ 205
B	4-10 minimum salaries	34	36	R$ 68
C	0-4 minimum salaries	51	16	R$ 20

Source: ABIFARMA 1998

23. The consumption of pharmaceuticals is concentrated in Brazil, with a little under half of the market share is situated in the states of Sao Paulo and Rio de Janeiro. The pattern of pharmaceutical activity is not surprising because it corresponds to more general economic trends and market demand.[31] This geographical concentration could be offset by a government that ensures the provision of basic medicine supplies throughout the country and/or to creates incentives for the private sector to assume a greater role in drug supply and distribution in less populated areas, particularly in the interior of the country. One possible option is for the government to consider is the creation of tax incentives for the private sector to enter into under-served markets.

Box 2. FURP's Basic Pharmaceutical Programme: *Dose Certa*. The State of Sao Paulo runs a comprehensive basic medicine programme. Drugs used in the public supply system are manufactured at A Fundacao para o Remedio Popular (FURP), one of eighteen public manufacturers in Brazil. FURP's basic pharmaceuticals programme (*Dose Certa*) services about 16 million persons or about one-third of Sao Paulo's population. *Dose Certa* provides a basket of 40 basic generic drugs, defined by a committee of doctors, pharmacists and public health specialists, to the 645 municipalities in the state. Drugs are supplied directly to the health service facility from the manufacturing site. The programme operated with a budget of about R$ 20 million in 1997.

Table 3. A Sector Snapshot

ITEM	APPROXIMATE NUMBER
Manufacturers (Public and Private)	**400**
Pharmacies	**45, 000**
Hospitals, Health Centers	**5, 000**
Wholesalers\Distributors	**1, 000**
Number of Products	**5, 200**
Number of Presentations	**9, 200**
Firms Directly Involved in Sector	**47, 100**
Firms Indirectly Involved in the Sector	**250, 000**

Source: ABIFARMA, 1998

[30] Minimum salary is about US$ 100 per month.

[31] The States of Sao Paulo and Rio have a collective population of about 71million (based on 1998 figures).

Main Sector Issues

4.1 The Main Problems

24. Based on interviews with stakeholders, there are five main weaknesses in the pharmaceutical sector which are relevant for the Bank's broader health sector work: (1) the insufficient implementation and enforcement of drug regulations which can assure that quality standards are in place (such as Good Manufacturing Practices (GMP)); (2) insufficient and sometimes inappropriate supplies of publicly funded basic medicines; (3) weak human and institutional capacity for drug procurement at the federal, state and local levels; (4) self-medication which can lead to drug resistant viruses if only a partial course of treatment is consumed;[32] and, (5) an absence of bioequivalence and bioavailability testing for generic drugs.

4.2 Equity and Efficiency of Public Pharmaceutical Expenditures

25. The public expenditure allocated to pharmaceuticals represents a small percentage of the federal health budget (about 5%). The table below shows estimates of federal expenditures on drugs for 1999. Precise public expenditures on pharmaceuticals are difficult to assess in Brazil, as they are dispersed among different health programmes at the federal level (e.g. strategic drugs, communicable diseases, and basic medicines). Real federal drug spending, then, is higher than indicated in the data shown, because the data do not include the drug funding which the government pays to public and private hospitals and clinics, contracted by SUS. The municipalities and states also supplement pharmaceutical budgets; their contributions vary widely. Drug expenditures should be assembled into a central data base, so more precise estimates are made possible.

Table 4. Brazil's Federal Drug Budget 1999

ITEM	Amount in R$
AIDS and STD Drugs	315,677, 535
Essential and Other Drugs	375, 416, 520
TOTAL	**691,094, 055**

Source: Ministry of Health

26. The policy implications of the above data are many, even with the knowledge that the numbers do not represent total drug expenditure. Is the government spending its pharmaceutical budget efficiently and equitably, particularly when it has little control over its priorities given the constitutional right of health care? Is it maximizing the impact of its pharmaceutical budget? How will the government cope with some of the financing precedents it has set? Because of the strength of the AIDS lobby, the government commits about one-third of its total drug budget for AIDS drugs, which are consumed by a small number of the population (about 536, 000). The development of new drug technologies, which can improve quality of life of persons and reduce the need for costly health services, will continue to present challenges for

[32] Poor quality drugs can also lead to viruses which are immune to all treatment drugs.

the government about how it chooses to spend its pharmaceutical budget, and who should have access to new drug therapies.

4.3 Pharmaceutical Supply and Distribution

27. The decentralisation of the pharmaceutical supply and distribution system has not lessened the rigidity of the delivery system, and has resulted in ambiguity about the specific duties and responsibilities of the municipal, state, and federal governments. This has been addressed recently by the development of a National Drug Policy (Regulation 3916, October 1998). Pursuant to it, the roles and responsibilities of the three spheres of government are clearly defined for the management of medicines. The approach taken by the *Departamento de Assistencia Farmaceutica* of the State of Ceara could be a model for others. State and municipal financial resources are itemized specifically for drug procurement, and spheres of authority for the sector are defined clearly for each level of government.

Best Practice #2 Features of a Well-Run Distribution System

- ❑ Maintains a constant supply of drugs;
- ❑ Keeps drugs in good condition
- ❑ Minimizes drug losses due to spoilage and expiry
- ❑ Rationalizes drug storage points
- ❑ Uses available transport as efficiently as possible
- ❑ Reduces theft and fraud in the supply system
- ❑ Provides information for forecasting drug needs

Source: Managing Drug Supply, Second Edition, 1997, MSH and WHO.

28. Until May 1997, the public pharmaceutical supply system in Brazil was centralized under CEME (Central de Medicamentos), which was set up by the military government in 1971. The rationale for CEME was that it would function as a complement to the existing health insurance system by providing medicines for those who were too poor to buy them. CEME soon expanded from supply to production. By 1973, it was not only acting as a pharmaceutical supplier, but also supporting research on basic pharmaceutical inputs, such as raw materials. National self-sufficiency in medicines was perceived as a strategic, national security and sovereignty issue, as well as a vital component of a national health policy.

29. CEME was viewed by many as an ineffective and corrupt agency, which had particularly deleterious consequences for the poorest. In part, this was because CEME's institutional logic became more directed towards satisfying the interests of the public and private Brazilian manufacturers, than towards meeting the needs of the state and city health departments, by supplying them with essential drugs for their populations.[33] Losses of medicines distributed by the agency were high owing to expiration of products and unsuitable storage conditions. The procurement methods which the agency applied were viewed as non-transparent and corrupt.

[33] Peter B. Evans " Foreign Investment and Industrial Transformation: A Brazilian Case Study." Journal of Development Economics 3 (1976) p. 133.

30. After CEME's closure in 1998, the federal government developed a transitional drug supply programme, Farmacia Basica, which supplied a kit of essential drugs (32-40 items) to municipalities with populations under 21,000 persons. Approximately 75% of the municipalities in Brazil fit this category. The Ministry of Health reported that the number of municipalities it indirectly supplied through this programme was 1,467 and it directly distributed to 2,732 municipalities. The drug kits supplied by the programme were selected on the basis that they could cover the basic health needs of about 3,000 persons for a period of three months. The interim programme was viewed as ineffective by some health specialists because the pharmaceutical needs of the country vary from region-to-region and the uniform drug kits did not reflect the different epidemiological profiles found in the country. As a result, there were problems of wasted drugs and unmet basic pharmaceutical needs for the population. Despite its imperfections, the programme was a necessary part of transforming the government's pharmaceutical supply system from a centralised to a decentralised model.

31. As of 1999, the Government transfers funds for basic medicines directly to the states and municipalities. On a per capita basis, the federal government finances R$ 1 and the state and municipal governments finance at least R$ 1 together (states and municipalities negotiate how much they contribute). The federal government's contribution is R$ 160 million for basic medicines in 1999, a significant increase from 1998--R$ 45 million. R$ 2 is budgeted for each person's basic drug needs or about R$ 320 million. The federal government continues to finance strategic drugs for diseases such as AIDS, TB, diabetes, and leprosy.

32. It is still to early to tell how the new system will impact the poorest members of the population, particularly for those in remote regions in the country, such as Amazonas, even if the federal government still assumes responsibility for the drug supplies in these areas. Unless good procurement techniques are used (see below), the consequences of the decentralisation could be damaging from both an economic and health point of view. As Medici and others have emphasized, decentralisation of the pharmaceutical supply to the municipalities is desirable only for those larger cities which have sufficient managerial autonomy (and capacity).

Best Practice #3 Core Principles of Public Pharmaceutical Procurement

- Procure the most cost-effective drugs in the right quantities to treat prevailing health problems in the majority of patients served.
- Assure drug product quality through supplier selection, monitoring of supplies, and quality assurance programmes.
- Ensure timely delivery of products to health facilities and to patients.
- Achieve the lowest possible total cost taking into account purchase price, hidden costs, holding costs and operating costs.

SOURCE: Guidelines for Good Procurement Practices, Interagency Pharmaceutical Coordination Group

33. Most local governments in Brazil do not have the human and institutional capacity to manage the procurement and distribution of pharmaceuticals effectively.[34] The administrative work required in this type of set up is likely enormous. There are some 5,500 municipalities in Brazil and the government is supposed to draw up a contract with each one. Should the procurement and logistics be performed by the government if quality and low prices through the exercise of market power are the goals of the government? Strengthening drug procurement capacity will require a change in the "rules-of-the-game," and training of personnel to ensure that capacity is built. The use of contracting out procurement processes to private procurement agents could also be considered in some cases.

Best Practice #4 The Chilean Drug Purchasing Model. In Chile the central purchasing agency (CENABAST) no longer is responsible for bulk purchasing, storage and sales to individual hospitals. Instead, it acts as an intermediary between the hospital purchasers (who opt to use it)and the drug suppliers -- a broker and purchasing agent --for groups of hospitals interested in some products. Hospitals define what they need, and pay the providers directly. Pharmaceutical companies deliver the products directly to the relevant hospitals. An electronic bidding system on behalf of the hospitals has also been set up in an effort to ensure their stronger purchasing power [35]

4.4 Drug Laws and Regulations

34. Based on interviews with representatives from the public and private sector, drug regulations is an areas which is identified commonly as weak. Evaluation, registration, surveillance, audits, and inspections are not being carried out as they should, partly as a result of government budget constraints and insufficient technology. There is also a limited knowledge base among inspectors, which indicates their need for training. Inspectors require basic education, as an example, on what a reference standard is, and what it is used for. Good career incentives are also required for them to do their job professionally. The enforcement of drug regulation depends heavily on the strength of the judicial system as well.

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[34] Ibid.

[35] Jorge Carikeo Monyota, "El Analisis de la Reforma del Sistema de Abastecimiento del Sector Salud en Chile." Draft, 1/08/98.

35. Lessons learned from other countries, and even from other sectors, such as telecommunications, could be instructive for Brazil as it embarks on regulatory reforms. The government should set up an institutional framework which does not generate conflict of interest. For example, if the Ministry of Health is a major purchaser of drugs, the health agency which regulates drugs should be an autonomous agency, and not under its jurisdiction. Regulations should also control but not damage private sector activities. Other lessons which could be applied to the Brazilian case are: (1) ensuring regulatory institutions are sufficiently autonomous so they are not influenced heavily by political agendas; (2) ensuring that there is enabling legislation in place which will provide institutions with the flexibility they require to set and enforce rules; and, (3) giving institutions adequate resources for the development of information systems and the maintenance of inspectors.[36] And, efforts should be made to implement a regulatory system which functions on observable and verifiable quality control mechanisms, monitored on a regular basis.

4.5 Counterfeit and Sub-Standard Drugs

36. Pharmaceuticals are particularly susceptible to counterfeiting because they are a high profit and low bulk product. In Brazil, examples of counterfeit drugs include: [37](1) capsules of the anti-epileptic phenytoin contained barely 25 percent of the labeled amount; (2) fake penicillin and tetracycline products contained only a small portion of the labeled amount of the antibiotic, or none at all; (3) Schering do Brazil produced 2257 kilos of the contraceptive, microvlar, to test a packaging machine, but only controlled for the disposal of 600 kilos; and, (4) *Botica ao Veado d'Ouro* , a local producer in Sao Paulo, produced and distributed a counterfeit drug used for patients with prostrate cancer. Estimates about the percentage of counterfeit drugs in the Brazil market are inconsistent. The National Secretariat of Health estimates that about 5 to 7 per cent of all medicines in Brazil are counterfeit. Some private sector representatives estimate that the presence of fake drugs represent only about 0.4 per cent of products sold in Brazil's non-hospital pharmacies. [38]

[36] These points are cited from Daniel Whitaker's article on "The Future of Managed Care in Latin America" pp. 143-154 in Clemont Bezold, Julio Frenk and Shaun McCarthy (eds.) 21st Century Health Care in Latin America and the Caribbean: Prospects for Achieving Health for All. (Mexico City: Institute for Alternative Futures and Fundacion Mexicana para la Salud, 1998). Used with permission from the author.

[37] The following examples are from cited in "The Drug Swindlers" op. cit., p. 154.

[38] Pharmaceutical research-based industry figures.

37. Brazil is classified by UNIDO as a country with pharmaceutical reproductive capabilities; it produces both therapeutic ingredients and finished products.[39] Domestic producers produce about 30% of the drugs consumed in the market and multinational companies, account for the remainder. Brazil has 11 public producers registered with the Associacao Nacional dos Laboratorios Oficiais: Fundazao Ezequil Dias (MG), Centro de Medicamentos do Parana, Laboratorio Farmaceutico de Pernambuco, Fundacao Oswaldo Cruz (RJ), Instituto Vital Brasil (RJ), Laboratorio do Rio Grande do Sul, Laboratorio de Santa Catarina, Nucleo de Pesquisas de Alimentos e Medicamentos do Rio Grande do Norte, Laboratorio Farmaceutico de Alagoas, Bahiafarma, Industria Quimica de Goias. There is also Fundacao para o Remedio Popular (SP).

38. Brazil's public manufacturers have been largely responsible for supplying the basic medicines which are distributed throughout the public health system. They are financially assisted by tax exemptions. The government's efforts to improve the enforcement of drug quality standards in Brazil may mean that many of these facilities will have to receive investments in order to ensure their quality standards are up to international levels. The role of how the private sector can become more involved in supplying drugs to the poorest members of the population, particularly in under-served areas, should be considered seriously by the government.

39. In the past, manufacturers in the public and private sectors have not been consistently subject to sufficient monitoring for GMP standards, nor rigorous testing of product quality. The same applies to raw materials (about 60%-70% of raw materials for pharmaceuticals are imported in Brazil).[40] Previous governments have made intermittent efforts to improve the quality standards in the pharmaceutical sector in these and other areas. For example, the inspection of manufacturing plants improved from 1995-1996, when the number of inspections carried out by the drug inspection team was 740. This compares with only 25 which had taken place from 1993-1994, 340 re-inspections were also executed during the same time period.

[39] Robert Balance, Janos Pogany and Helmut Forstner, 1992. "The World's Pharmaceutical Industries: An International Perspective on Innovation, Competition and Policy." UNIDO

[40] SCRIP, February 10, 1999, Issue No. 1410.

Table 5. Medicines that Escape Regulation

TYPE	DESCRIPTION
PIRATED	Pirated drugs are those drugs which are produced in breach of intellectual property law. They are copies of new drugs which are protected by patents and are not available yet for legitimate generic production. They contain the components of the authentic product but many governments do not require bioequivalence and bioavailability data based on human clinical trials. Pirated drugs are subject to legal remedies under commercial law.
COUNTERFEIT	Counterfeit drugs are packaged and labeled to mimic an original product. Often, they do not contain any or a sufficient amount of the active ingredients of the original product. They are sold under the false pretense of having pharmacological properties. Management of this problem requires a sound regulatory framework and inspection system.
SUB-STANDARD	Sub-standard drugs do not meet international standards (such as in adherence to Current Good Manufacturing Properties). There is no guarantee that these drugs contain the appropriate amounts of active materials, that they are bioequivalent and bioavailable, that they are packaged properly, and that they will remain intact, physically and pharmacologically, prior to their expiration date. Management of this problem requires a sound regulatory framework and inspection system.

4.6 Pharmacovigilance

40. Pharmacovigilance[41] is an essential component of a quality assurance system and is an area where Brazil could benefit from making investments, particularly to set up a national network of laboratories. Equally important, is a good information system which can detect, notify, and analyse the effects of adverse drug reactions. A good information system can then permit the government to make sound decisions concerning the restriction of certain drugs in the market. There have been a number of initiatives in the past to implement a national pharmacovigilance system, but because of the high turnover of leadership in the then Sanitaria Vigilancia de Saude (SVS), as well as within the Ministry of Health, no system has been fully set up. Still, a few institutes in Brazil have developed excellent pharmacovigilance systems which cover small areas. The *Grupo de Prevenca ao Uso Indevido de Medicamentos (GPIUM),* based at the Federal University of Ceara Forteleza, is an example. GPIUM executes "Programa de Notificacao Voluntaria de Reacoes Adversas a Medicamentos" (Programme of Voluntary Notification of Adverse Reaction to Medicines) in agreement with the Secretary of Health of the State of Ceara. Good communication between the government and the private sector is also critical in pharmacovigilance.

[41] Pharmacovigilance is the monitoring of adverse drug reactions on a regular basis.

4.7 The National Health Surveillance Agency (Agencia Nacional de Vigilancia de Sanitaria (ANVS))

41. Legislation for the creation of a new health agency (ANVS) was passed by the Brazilian Congress in early 1999. The ANVS began its operations in Brasilia, following a presidential decree establishing the agency and the naming of five directors in May 1999. The new agency oversees pharmaceuticals, as well as medical equipment, cosmetics, and hospital services. It also has responsibility for authorizing products on the market (*registro sanitario*), as well as the licensing of manufacturers (*licenca da funcionamento*). The agency is responsible for overseeing an estimated US$ 120 billion worth of services and products, or about 15% of the GDP. A recent report by the US Department of Commerce notes the law which created the ANVS also instituted a new user fee structure, together with new certification rules. The last date the old user fees could be charged was May 10, 1999. From this date on, the local market started paying new user fees for new drug registrations, which increased by 90 (ninety) times over the old values. The government's increase of user fees, coupled with delays in registration, resulted in a number of legal actions against the government of Brazil by local trade associations, which are under review.[42]

42. It is important to note that the core functions[43] of a regulatory agency are: post-marketing surveillance, GMP inspection, distribution inspection, regulation of promotion, and the authorization of clinical trials. All of these areas need sufficient capacity. An effective agency also requires trained staff with appropriate career incentives, who can ensure that regulations are implemented and enforced.

4.8 Drug Registration Procedures

43. The registration process of new pharmaceutical products is based on Brazilian Law 6360 (1976), the Administrative Act number 71/96 (1977), as well as other regulations which are issued by the Ministry of Health. There is, in theory, a 90 day review period for a drug application for registration but processing can take anywhere from 8 months to a year. Registration of AIDS drugs are the exception. They commonly are registered by the government in less than a month

44. Since 1976, in practice, local industry has marketed its products according to local court orders. These orders guarantee producers the right to sell a product after the 90 day term for a government review has expired. Thus, for the government to effectively mange the registration, it needs the capability to respond in 90 days or less, which is not typically the case (often drug registration can take as long as a year). This "administrative silence" is criticized by some regulatory experts[44] because it can potentially mean a lack of control of the kinds of drugs available in the market. Much more needs to be known about how to manage the registration system better and the impact of existing practices.

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[42] Clovis Lemes, "Brazilian Medical Equipment Sector" August 18, 1999.
[43] Julie Milstein, WHO, Geneva, draft, Regulation of Vaccines: Building on Existing Drug Regulatory Authorities.
[44] Based on discussions with FDA staff.

45. The scale for drug registration fees has recently been modified. They are now determined by firm size and the type of product. Fees for the registration of new medicines range from R$ 8,000 to R$ 80,000, similar products R$ 2,100 to R$ 21,000, and generic drugs from R$ 600 to R$ 6,000.

Best Practice # 5 Computerization of Drug Registration in the Phillipines

"In 1993 and 1994, the Bureau of Food and Drugs (BFAD) in the Philippines undertook a project to computerize drug registration. Different offices involved in the registration process were connected by a terminal to a common database running under a UNIX mulituser operating system. Separate terminals were set up for entering initial product information for product evaluation functions, for the laboratory, and for the office of the director, where final decisions are made. Another terminal was made available for clients to inquire about the status of their applications. Reports can be generated using a report generator in the software system. These are not preformatted reports that can be generated at a "click of the button" but are customized for responding to questions or requests for information. Use of the report generator has required training. Development of this new computerized system required streamlining of the registration system itself through a process of on-going feedback and revision. After installation, the old and new systems were run in parallel until the new system was shown to be reliable. Staff within BFAD participated in both development and installation to ensure sustainability and maintenance of the system. Although there was some initial resistance to the new system, it has speeded up the registration process and is now well accepted by BFAD staff. "

Source: Brudon-Jakowitz (1994) in Managing Drug Supply, 1997, p. 97.

4.9 Pricing Policies

46. Brazil had a price control system in place until 1992, when pharmaceutical prices were allowed to increase only at a rate below inflation. Prices were incrementally liberalised as part of the Collor Government's economic plan. WHO characterizes Brazil's price controls as "*monitored freedom*" because prices are controlled through voluntary arrangements between the government and the pharmaceutical industry. In practice, no price regime is in place, even though the government is formally responsible for approving the prices of new pharmaceutical products.

47. Pharmaceutical companies are responsible for determining wholesale drug prices, but the prices which the consumer pays at the pharmacy also reflects other costs and taxes. Prices for retail drugs also include a pharmacy mark-up (which can be as high as 30%), a federal tax (PIS/COFINS) of 6% and a state tax (ICMS), either 17% or 18% depending on the state (see Box 3 below). The ANVS is undertaking an investigation of pharmaceutical prices at the retail and wholesale level. The work is initially being carried out by two economic research institutes, IPEAD in Minas Gerais and FIPE in Sao Paulo, and will likely be expanded to other states. The Ministry of Health plans to use the information to set up a monthly pharmaceutical retail price index.[45]

[45] Scrip "Brazil Compiling Pharma Price Data" August 4, 1999, Issue No. 2460, p. 17.

Box 3. Example of Drug Pricing Structure

PUBLIC PHARMACEUTICAL PRICE:	R$ 142.86	100 %
SALES TAX (ICMS)	R$ 25.71	18%
PIS\COFINS	R$ 8.71	6%
GROSS MARGIN – WHOLESALER	R$ 9.69	7%
GROSS MARGIN – RETAILER	R$ 31.37	22%
NET MANUFACTURER SELLING PRICE	**R $ 67.38**	**47%**

48. Pharmacoeconomics may be a tool the government could apply to help it make more cost-effective drug purchasing decisions. Pharmacoeconomics is a methodology for purchasing drugs, based on data that link the net costs of drug use to meaningful changes in health status, compared with data on alternative therapeutic or preventive approaches. Governments like Australia, the United Kingdom, and even private purchasers (e.g. HMOs) in the United States are applying this methodology to make better purchasing decisions. The use of pharmacoeconomics allows decision makers to determine what is the "added value" of a drug and so they can determine whether the "added value" warrants the drug price. In short, drug resources can be spent more strategically and effectively with the use of this methodology.

4.10 TRIPS and Generic Drugs

49. Brazil is a member of the World Trade Organisation and is transforming its intellectual property system because of commitments it made under the TRIPS (Trade- Related Aspects of Intellectual Property) Agreement. The TRIPS Agreement allows developing countries a general transition period of up to five years to amend their patent legislation so it is in accordance with international standards. Ten years is allowed for developing countries which have not provided product patent protection for pharmaceuticals. Least developing countries are given 11 years with the possibility of extending that period to harmonize their regulations with international standards. Brazil's new patent law, which took full effect in May 1997, achieved early compliance with most of the TRIPS requirements, including the provision of patent protection for pharmaceutical products.

50. In November 1998, the House of Representatives passed a generic drug law, which was spearheaded by Deputy Eduardo Jorge. Senate approval for the legislation was passed in January 1999, and regulations are being developed. The legislation, aimed at promoting the use of generics, took eight years for approval, and requires that generic names be printed on product packs, and used on prescriptions and for purchases under SUS.[46] Sound bioequivalence and bioavailability testing is essential for consumers to have confidence in the quality of generic drugs.

51. The Ministry of Health announced that the legislation would potentially allow for a 40-45% reduction of pharmaceutical prices and Minister Serra has promised to provide incentives for manufacturers of generic drugs.[47] The legislation makes it

[46] Scrip No. 2452 p. 20, July 07, 1999.
[47] Correio Braziliense, November 19, 1998, p. 12.

mandatory for the generic name to be included on all product packs (at least half the size of the brand name) and requires that under SUS, all prescriptions be written by their generic name, and that generic drugs be used in all purchasing proposals and contracts[48]. Bioequivalence and bioavailability,[49] as well as in vitro testing, are essential to guarantee the quality of generic drugs in the market. The private sector has technical expertise in these areas which it could share with the government to help ensure the quality of the drugs in the market.

Table 6. Per Capita Drug and Health Expenditures (US$) in Select Developing Countries (1990)

Country	Drugs	Health
Bangladesh	2	6
Brazil	16	146
Chile	30	100
China	7	11
Costa Rica	37	132
Ghana	10	21
India	3	21
Indonesia	5	12
Kenya	4	16
Mexico	28	89
Morocco	17	26
Mozambique	2	5
Pakistan	7	12
Philippines	11	16
Turkey	21	76

Sources: MDS 1997: Drug expenditures from Ballance et al. 1992; health expenditures from Murray and Lopez 1994[50].

4.11 Priority Setting

52. Improvements in the pharmaceutical sector will require the government to focus strategically in a number of core areas. The following are recommended areas for government intervention:

1. Better enforce drug regulations.
2. Improve supplies of cost-effective, good quality publicly funded drugs.
3. Strengthen public procurement capacity and/or better use of private agents.
4. Improve drug use.
5. Build stronger public and private sector partnerships.

[48] SCRIP, World Pharmaceutical News, February 5, 1999, Issue No. 2409, p.17.

[49] Bioavailability " refers to the rate and extent to which the active substance is absorbed from a pharmaceutical dosage form, and becomes available at the site of action. Two products are deemed to be bioequivalent if their bioavailabilities after administration in the same molar does are similar to such a degree that their effects, with respect to safety and efficacy will be essentially the same."[49]

[50] Balance R., J. Pogany, and H. Forstner 1992, The World's Pharmaceutical Industries: An international perspective on innovation, competition, and policy, UNIDO, and C. Murray and D. Lopez (eds.) 1994. Global comparative assessments in the health sector: Disease burden, expenditures, and intervention packages, Geneva, WHO.

53. This paper has been exploratory in nature, identifying areas in which policy changes, investments, or changes in practices could improve the organization and functioning of the Brazilian pharmaceutical sector. Without assuming that strong conclusions are possible at this point, the table below lists actions that could help the government reach the above objectives:

5. Action Plan

Action Area	Recommendation
Better enforce drug regulations	Brazil's creation of the ANVS presents an opportunity to take stock of the regulatory regime, and to ensure that the ANVS has the capacity to enforce drug regulations effectively. International experiences and standards should be evaluated, and appropriate best practices applied to the Brazilian context. The government is encouraged to meet with international experts to learn from country cases, and to form an action plan, with measurable outcomes, for making improvements in the regulatory system. This process could be initiated with partners, like PAHO, private and public industry, and international experts. The government could also participate in international drug harmonisation initiatives to ensure that Brazil is sufficiently in line with international standards.
Improve supplies of cost-effective, good quality publicly funded drugs	Current approaches and mechanisms for the supply of basic medicines should be studied, particularly in view of decentralisation, to answer the question of why there is not sufficient pharmaceutical coverage. Particular focus should be placed at the municipal level. This study should include an economic analysis of the individual pharmaceutical products. Mechanisms ought to be developed to ensure the creation of incentives for improving supplies of drugs in underserved areas. A pilot study could be launched in one state, such as Bahia, and then extended to others.
Strengthen public drug procurement capacity and/or better use private agents	Different models of procurement should be evaluated (e.g. open tender versus restricted, bulk procurement, electronic procurement (Chile)) and implemented in different states/municipalities. The models should then be evaluated with particular emphasis on how well they guarantee drug supplies for the poorest. Training in tender management and other core areas of procurement should accompany this pilot study at the central, state, and local levels.
Improve Drug Use	Patterns of drug use should be assessed from a regional and economic perspective. The government could cost-effective targeted investments to promote rational drug use among patients and health providers.
Build stronger public and private sector partnerships	There is a need for a new paradigm for private-public collaboration in the Brazil pharmaceutical sector. The government and the private pharmaceutical industry should meet regularly on neutral grounds to have open discussions about pharmaceutical policies. Industry can provide technical support to the government on specific areas, such as drug regulations and good manufacturing practices.

5.1 Recommendation for Future World Bank Activities

Undertake formal economic sector work to develop detailed evidence, to characterize the tradeoffs, and to understand the costs and benefits of action in the five action areas outlined above. Such a study would provide an opportunity for collaboration among one or two state and municipal governments, the federal government, and their international partners (WHO/PAHO, IDB, World Bank).

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