

**Access to Essential Medicines:  
State of Minas Gerais, Brazil, 2001**

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Final Draft May 2003

Strategies for Enhancing Access to Medicines Program  
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## About SEAM

The Strategies for Enhancing Access to Medicines (SEAM) Program is funded by the Bill & Melinda Gates Foundation under contract D3601, and works to improve access to essential medicines and vaccines in the developing world by fostering partnerships between the public and private sectors.

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## Recommended Citation

Center for Pharmaceutical Management. 2003. *Access to Essential Medicines: State of Minas Gerais, Brazil, 2001*. Prepared for the Strategies for Enhancing Access to Medicines Program. Arlington, VA: Management Sciences for Health.

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## Acknowledgments

For their contributions and cooperation, we would like to acknowledge the following—

### **Ministry of Health**

Carlos Alberto Pereira Gomes—Technical Manager, Pharmaceutical Support  
Silas Paulo Resende Gouveia—Chief of Staff, National Health Surveillance Agency

### **Federal University of Minas Gerais**

Francisco Eduardo de Campos—Coordinator of NESCON/School of Medicine  
Sabado Nicolau Girardi—Coordinator of the Research Unit on Market Signals/NESCON

### **State Health Department**

Júlio César Martins Siqueira—Superintendent of Health Surveillance

### **Management Sciences for Health/Brazil**

Karen Johnson Lassner—MSH/Brazil Representative

### **Fundação Oswaldo Cruz (FIOCRUZ)**

Jorge Bermudez—Director, School of Public Health



## Acronyms

ABIFARMA	Associação Brasileira da Indústria Farmacêutica
ANVISA	Agência Nacional de Vigilância Sanitária (National Agency for Health Surveillance)
BRL	Brazilian real
CAF	Coordenação de Assistência Farmacêutica (State Pharmaceutical Care Office)
CEME	Central de Medicamentos (Center for Medical Supplies)
CEMIG	Companhia Energetica de Minas Gerais
CFF	Conselho Federal de Farmácia (Federal Pharmacy Council)
DEF	<i>Dicionário de Especialidades Farmacêuticas</i>
EDL	essential drugs list
ENSP	Escola Nacional de Saúde Pública
FIOCRUZ	Fundação Oswaldo Cruz
FUNED	Fundação Ezequiel Dias
GDP	gross domestic product
GMP	good manufacturing practices
HDI	Human Development Index
HMO	health maintenance organization
IBGE	Instituto Brasileiro de Geografia e Estatística (Brazilian Institute for Geography and Statistics)
IDPIG	<i>International Drug Price Indicator Guide</i>
INDI	Instituto Industrial de Minas Geiras
MOH	Ministry of Health
MSH	Management Sciences for Health
NDP	national drug policy
NESCON	Nucleo de Estudos em Saúde Coletiva e Nutrição
NGO	nongovernmental organization
PAMS	Pesquisa de Assistência Médico-Sanitária

PNAD	Pesquisa Nacional por Amostra de Domicílios
REME	Relação Estadual de Medicamentos (State Medicines List)
RENAME	Relação Nacional de Medicamentos Essenciais (National Essential Drugs List)
SEAM	Strategies for Enhancing Access to Medicines [MSH]
SSOH	State Secretariat of Health
SUS	Sistema Único de Saúde (Unified Health System)
TELEMIG	Telemar Minas Gerais
TRIPS	[Agreement on] Trade-Related Aspects of Intellectual Property Rights
UERJ	Universidade Estadual Rio de Janeiro
UFMG	Universidade Federal Minas Gerais
USD	U.S. dollar
VSE	Vigilância Sanitária Estadual (State Health Surveillance Office)
WHO	World Health Organization

## Executive Summary

Although Brazil ranks as the eighth-largest economy in the world and boasts of a sophisticated health sector, there are great disparities among regions and socioeconomic groups in the distribution of wealth and health. A pioneer in the concept of essential drugs, Brazil recently adopted ambitious policies and strategies to enhance equity in access to basic health services. Evidence indicates, however, that reforms have not yet had their full intended impact in the least developed regions of the country; therefore, it is reasonable to explore alternative models for the management of health and pharmaceutical services in these regions. This report presents the results of an assessment conducted in one of the more remote and underdeveloped regions of the state of Minas Gerais. The access gaps identified include a critical lack of availability of drugs in the public sector (while the private pharmacies were well stocked), limited accessibility to pharmaceutical services and products in terms of hours of operation in the public sector, lack of access to and use of quality information about pharmaceuticals, and poor product quality.

A strategy has been formulated to address the access gaps that are most significant and most amenable to change. The strategy utilizes existing private sector channels to support functions that the public sector, for various reasons, is not carrying out efficiently. This support is to be provided through a partnership between sectors in which specific functions are assigned to each. The public sector would retain the functions of selection (of drug manufacturers, distributors, and dispensers), prescription (at Sistema Único de Saúde clinics), and administration (including auditing and quality control). The private sector would take on the functions of production, distribution, and dispensing of medications in support of existing public sector entities.

By identifying those aspects of access that have significant potential for improvement, and by selecting existing channels and administrative structures, when feasible, to bring about such improvement, the chances of success and the impact are maximized and the resources and efforts required minimized.



## Introduction and Background

In 2000, Management Sciences for Health (MSH) received a grant from the Bill & Melinda Gates Foundation to identify and test innovative approaches to improving access to essential medicines in developing countries through greater participation of the private sector. To fulfill this mandate, MSH set out to implement programs to promote access, design a method to measure the nature and extent of the lack of access to essential medicines, and monitor the impact of these programs.

The Strategies for Enhancing Access to Medicines (SEAM) access framework was developed after a review of the published and unpublished literature on access to health care in general and medicines in particular. This framework was later discussed at a consultative meeting jointly sponsored by MSH and the World Health Organization (WHO), in Ferney-Voltaire, France, held December 11–13, 2000. More than 40 experts from 15 countries participated in the discussions and concluded that, as with health services, the concept of access to essential medicines is a construct that has several distinct dimensions that are distinguished by sets of specific relationships.

The following four dimensions of access emerged from the discussions—

- Physical availability, defined by the relationship between the type and quantity of product and service needed and the type and quantity of product and service available
- Affordability, defined by the relationship between the products and services and the user's ability to pay for them
- Geographic accessibility, defined by the relationship between the location of the product or service and the location of the potential user of the product or service
- Acceptability (or satisfaction), defined as the fit between the user's and provider's attitudes and expectations about the products and services and the actual characteristics of these products and services

In addition, quality of products and services was defined as an essential component that cuts across all dimensions. A set of 17 key indicators was developed to represent the four dimensions of access and one crosscutting characteristic. The indicators are detailed in the Access to Essential Medicines, Vaccines, and Related Health Commodities section of this report.

After several rounds of internal discussions and consultations with experts from WHO and the World Bank and with contacts in developing countries, six countries—Ghana, Tanzania, Cambodia, India (state of Rajasthan), Brazil (state of Minas Gerais), and El Salvador—were identified as countries where assessments based on the conceptual framework would be undertaken, with the understanding that only two, or at most three, countries would eventually be selected for long-term projects under the SEAM Program. The initial selection criteria included

perceived or known significant lack of access to essential medicines, perceived enabling environment for private sector initiatives, political and economic stability, and potential for collaboration with other MSH and Gates-funded local initiatives.

The assessments were carried out between February and May 2001. Local private, not-for-profit, and academic organizations collaborated in the adaptation of data collection instruments, sample selection, data collection, and analysis. This report presents the assessment results and proposal for the state of Minas Gerais, Brazil. It is expected that the countries not selected for long-term assistance will have benefited from the assessment exercise, in particular from a SEAM-supported analysis of potential public-private sector initiatives to enhance access to essential medicines. With such an analysis in hand, the country can approach donors and lenders to finance such work, as appropriate.

### Country Overview

#### *Geography*

Brazil, the largest country in Latin America, is divided into five geographical regions with different demographic, economic, social, cultural, and health characteristics. The state of Minas Gerais is itself a very diverse state that is frequently referred to as a microcosm of Brazil. With an area of 588,384 square kilometers, Minas Gerais is one of the largest states in the country. Situated in the central region, it borders the wealthier coastal states of Rio de Janeiro and São Paulo to the east and south, Goiás (where the capital, Brasília, is located) to the west, and Bahia to the north. The northern part of the state has a semiarid tropical climate, and the central southern area is semihumid tropical. Other areas of the state are mountainous and have a high-altitude tropical climate. This study was conducted in the northern part of the state.



#### *Demographics*

The population of Brazil is more than 170 million and is heavily concentrated along the coast and in urban areas. The country is a federal republic with 27 states and more than 5,000 municipalities; most of the municipalities have populations of fewer than 50,000. The demographics of Minas Gerais mimic the country's patterns. There are nearly 600 municipalities in Minas Gerais, inhabited by about 17.8 million residents. Like the country as a whole, about 80 percent of the population in Minas Gerais lives in urban areas, the largest of which is Belo Horizonte, the state capital.

In recent decades, Brazil has been experiencing a demographic transition characterized by a growing elderly population and shrinking younger population. The epidemiological profile of the

country reflects an increasing incidence and prevalence of chronic degenerative illnesses associated with increased longevity. However, a pattern of mortality remains that is generally linked to poverty and low quality of medical service (Andrade and Lisboa, 2001). In Minas Gerais, life expectancy (67 years) and infant mortality rates and patterns (32.2/1,000) are similar to those for the country as a whole.

## ***Social and Economic Development***

Brazil is one of the top 10 largest economies in the world. The country has a transitional economy with a strong industrial and commercial agricultural base. However, the distribution of wealth in Brazil is among the most uneven and disparate in the world. In 1999, an estimated 45 percent of the population lived in conditions of poverty, defined as less than 66 U.S. dollars (USD) per capita per month. The 1998 Human Development Index (HDI)—an index based on life expectancy at birth, level of education, income, and access to resources (Table 1)—ranks Brazil as 62 of 174 countries, but only the states in the south and southeast regions have levels of development that would be considered high (UNDP, 1998; World Bank, 2000). The HDI for the state of Minas Gerais in 1991, the last year for which this information is available, was 0.699; the average 1991 HDI for the specific region in Minas Gerais where the indicator study was carried out was 0.482, about the same level as Ghana today. Although this data is 10 years old, the figures are believed to be similar today (see Annex A).

**Table 1. Human Development Index Data, Brazil**

Components	Year of Survey			
	1997	1998	1999	2000
Life expectancy at birth (in years)	67.8	68.0	68.4	68.6
Literacy rate (percentage of population)	85.3	86.2	86.7	86.3
Education	78.9	83.0	84.6	84.6
GDP per capita	6.480	6.625	7.037	7.625

Source: Instituto de Pesquisa Econômica Aplicada (IPEA), 2002.

Note: GDP = gross domestic product.

## ***Infrastructure***

### *Electricity*

The best electric power infrastructure in Brazil is in Minas Gerais. The installed capacity of the Minas Gerais hydroelectric power plants is 12,000 megawatts, about 20 percent of the Brazilian total (Table 2). According to Companhia Energetica de Minas Gerais (CEMIG), the state power company, power generation in Minas Gerais is currently 25 percent above the state's consumption. However, during the month when this assessment was conducted, the state

experienced several blackouts and brownouts that caused businesses and schools to alter their schedules. The culprit was very low water levels at the hydroelectric plants caused by drought conditions.

**Table 2. Electric Power for Minas Gerais and Brazil, 1998**

	Minas Gerais	Brazil
Generation installed capacity (megawatts)	11,640	61,312
Industrial consumption (gigawatts)	23,949	124,699
Total consumption (gigawatts)	39,617	287,392
Percentage of total consumption used by industry	60	43

*Source:* Instituto de Desenvolvimento Industrial de Minas Gerais (INDI) ([www.indi.mg.gov.br](http://www.indi.mg.gov.br)).

### *Telecommunications*

Brazil has an extensive telecommunications system that reaches nearly every corner of the country. In the late 1990s, many public utilities, including the state telecommunications companies, were privatized in an effort to increase efficiencies by promoting competition. There are currently two fixed-telephone utilities in Minas Gerais—namely, Telemar Minas Gerais (TELEMIG) and CTBC Telecom; CTBC Telecom has a plant with over two million telephone terminals. TELEMIG handles 88 percent of the state grid, while CTBC Telecom is responsible for the remaining 12 percent. Both are connected to Embratel, the federal agency for long-distance national and international operations, and both offer a variety of services to commercial and residential clients.

All 853 Minas Gerais municipalities and more than 3,150 other locations in the state are provided with telecommunication services. The state already has over 130,000 kilometers of installed fiber-optic cables. TELEMIG’s digital network accounts for about 80 percent of the fixed-telephone grid in the state. Users can access telecommunication services through the Digital Network of Integrated Services as well as simultaneously speak on the telephone, navigate the Internet, or send a fax. The Maxitel, TELEMIG Cellular, and CTBC Telecom companies also operate mobile-telephone services in Minas Gerais.

Brazil has embraced the Internet as a medium for promoting participatory democracy and transparency. Most federal, state, and municipal actions are now posted on the Internet, including fiscal accounts. In support of this, the government of Brazil is seeking to subsidize the deployment of telecommunications infrastructure to impoverished and geographically isolated areas through its Universal Access Plan. In addition, Brazil’s postal service has launched a program called Porta Aberta, or Open Door, that provides the public with free access to Internet kiosks in post offices throughout the country’s largest cities. Indeed, there are several Internet providers operating in Brazil and in Minas Gerais. One public Internet company, Telemar, has two high-speed Internet stations with multiple terminals in the capital city of Belo Horizonte. A telephone card is all that is needed to access the Internet through this system.

However, although Brazil is home to 40 percent of South America’s Internet users, only 5 percent of Brazilians actually have Internet access. In 2001, as part of broader efforts to increase access to information technology, the Brazilian government commissioned university researchers to design the cheapest possible machine for accessing the Internet. In response, researchers from Brazil’s Federal University of Minas Gerais (Universidade Federal Minas Gerais [UFMG]) created a prototype of what’s being called the Popular PC. The first shipment of Popular PCs is meant to equip schools, libraries, and health centers with access to the Internet. The state-run bank, Caixa Econômica Federal, has agreed to provide loans to low-income households to purchase the computers.

### *Transportation*

Brazil has an extensive road and railway system (Table 3). The Minas Gerais highway system is one of Brazil’s best and longest. There are 19,076 kilometers of paved roads and 212,829 kilometers of unpaved roads. Many of these roads handle a considerable volume of interstate Brazilian cargo (e.g., approximately 9,000 cargo-hauling companies operate in Minas Gerais with a combined capacity estimated at 21,600 tons a month). Belo Horizonte, the state capital, is located at a key crossroad of major federal and state highways, which makes it easier for Minas Gerais to be connected to the main national urban centers, particularly Rio de Janeiro and São Paulo. The expansion of the highway that connects Belo Horizonte to São Paulo, the economic heart of South America, is expected to significantly enhance the economic status of the state.

The railway system in Minas Gerais represents about 5 percent of the total network in Brazil and includes both passenger and cargo trains. The train is an important mode of transport for commuters to Belo Horizonte.

**Table 3. Roadways and Railways, Minas Gerais and Brazil, 1997**

<b>Roadways and Railways (in Kilometers)</b>	<b>Minas Gerais</b>	<b>Brazil</b>
Paved roadways	19,076	151,256
Unpaved roadways	212,829	1,498,038
Railways	5,518	29,706

Source: INDI ([www.indi.mg.gov.br](http://www.indi.mg.gov.br)).

Mass transport and public transportation are much more developed in the urban areas. Residents in remote areas may have access to a road but often have limited access to vehicles.

### *Other Resources*

Brazil has many communications services. Minas Gerais alone has 35 newspapers and 350 radio stations. Minas Gerais also hosts 19 television generating stations and about 1,000 television

broadcasters. The only cable television company is in Belo Horizonte ([www.indi.mg.gov.br](http://www.indi.mg.gov.br)). An unknown number of households in the state boast satellite-based systems.

Full-service banking can be problematic for those living outside the major metropolitan areas. As of 1998, the state registered 46 banking institutions, but only 31 municipalities enjoyed full banking services. These banks had 1,785 branch offices and about 700 special outposts offering limited services ([www.indi.mg.gov.br](http://www.indi.mg.gov.br)).

## ***The Health Sector***

### *Organization of Health Services*

In 1989, health care reform was begun in Brazil. The existing uneven patchwork of poorly funded public services and sophisticated private services were supplanted by the Unified Health System (Sistema Único de Saúde [SUS]) after the 1988 Constitution clearly identified health care as a social right and an obligation of the state. The SUS aims to rationalize health care in Brazil through greater coordination of the three main health care subsectors (Almeida et al., 1999)—

- The public sector, which is publicly financed (about 56 percent of all health facilities are directly under the jurisdiction of the public sector, mostly at the municipal level)
- The portion of the private sector (profit and nonprofit) that is contracted or reimbursed by the public sector to provide services on its behalf
- The portion of the private sector that is financed solely by out-of-pocket payments or private health insurance (most specialized and hospital services in the country, primarily in the major urban centers, are offered through the private sector)

In 1999, Brazil had an estimated 56,133 health facilities. Almost half (47 percent) are health centers, and 26 percent are primary health care units and clinics. Hospitals account for 14 percent of all facilities, and 13 percent are diagnostic or supportive therapeutic facilities. Most (72 percent) health services in Brazil are linked to SUS (Table 4).

**Table 4. Distribution of Health Facilities by Type of Facility in Minas Gerais and Brazil, 1999**

Health Facilities	Minas Gerais (%)	Brazil (%)
Public facilities	(60)	(59)
Federal	36 (1)	628 (2)
State	81 (2)	1,930 (6)
Municipal	4,173 (97)	30,404 (92)
Subtotal	4,290 (100)	32,962 (100)
Private facilities	(40)	(41)
Private only	1,812 (64)	15,948 (69)
SUS	1,041 (36)	7,223 (31)
Subtotal	2,853 (100)	23,171 (100)
<b>Total</b>	<b>7,143 (100)</b>	<b>56,133 (100)</b>

Source: Instituto Brasileiro de Geografia e Estatística (IBGE), 1999.

There are 10 different legal categories of health services in Brazil. In addition to the public entities (federal, state, and municipal) and those of the armed forces (142 total), other categories include foundations, self-managed services, businesses, social services, cooperatives, union services, beneficent organizations, and philanthropies. Of these, the largest is philanthropies, which at 2,181 entities nationwide, accounts for 4 percent of all health facilities, most of which (73 percent) are hospitals (Instituto Brasileiro de Geografia e Estatística [IBGE], 1999).

Philanthropic organizations have special tax status and are eligible to receive SUS funds if they are registered with the Ministry of Health (MOH). These organizations may be run as a civil association with a particular social interest or, as is more often the case for health care, by a religious association. In the last 10 years, in large part due to the HIV/AIDS epidemic in Brazil, civil associations, including philanthropies, have taken a more active role in providing services. Nongovernmental organizations (NGOs) in general have also started to become more organized (Landim et al., 1999). However, there are some indications that the private and philanthropic sectors, rather than opting to contribute to the SUS, are finding other ways to fund their services, such as creating their own health plans (Alvarez, 1999).

Total health expenditure in Brazil in 1999 was USD 47.7 billion, 9 percent of the gross domestic product (Table 5). The public sector, essentially managed by SUS, is responsible for 40 percent of all health expenditure in the country.

Table 5. Health Expenditures in Brazil (1999)

Type of Spending	USD (Billions)	Per Capita	% GDP
Public	19.2	116.9	3.6
Private health plan	13.3	81.2	2.5
Out-of-pocket	15.2	93.0	2.9
Total	47.7	291.1	9.0

Source: Carlos Alberto Gomes, Secretaria de Políticas de Saúde, interview by M. Miralles, 2001.

Note: GDP = gross domestic product.

SUS supports services along four broad categories: hospital care, outpatient/ambulatory care, immunizations, and basic care (*atenção básica*). Several vertical disease-oriented programs (e.g., HIV/AIDS, tuberculosis, leprosy, malaria, mental health) aim to cover a variety of patient needs, and funding for these services follows the logic of the services. Some of these programs, most notably the HIV/AIDS program, are considered to be of strategic importance and have a specific organization. In the basic care category, the Community Health Agent Program (Programa de Agentes Comunitários de Saúde), is to be phased out and supplanted by the more comprehensive Family Health Program (Programa de Saúde da Família).

### *Management and Financing of Services*

The SUS management model has three levels (federal, state, and municipal), with ultimate responsibility for the provision and management of health services relegated to the municipal level. Each level is responsible for coordination of the system within its jurisdiction. This involves working with corresponding health councils and committees so that local-level input can be considered in the development and implementation of health programs. These local entities allow for the involvement of professionals and community representatives in decision-making and coordination efforts.

Providers that meet accreditation requirements can be registered with SUS and contracted to receive reimbursements for services provided to SUS patients. Such contracts should be managed, ideally, by municipal secretariats of health. However, not all municipalities have reached a level of management maturity that allows them to assume full responsibility (*gestão plena*). As of 2001, nearly all municipalities in the country had reached basic-level status, but only a few were qualified to assume full responsibility for fiscal management. Until they are, contracts are managed by the state. It is the state's responsibility to help the municipalities become capable of fiscal management. The new national health "smart card" (Cartão SUS), first implemented in 2001, will facilitate the administrative, financial, and managerial aspects of service provision.

The responsibility for financing public health care is shared among the three levels, with the federal government providing about 70 percent of the resources for public health and states and municipalities contributing about 15 percent each. Tracking the health budget per capita since health reform was undertaken presents a challenge because of the rapid devaluation of the

Brazilian currency and the decentralization of financing. However, the consensus is that, in both absolute and relative terms, funding for public health has increased steadily in the 1990s. The 2001 health budget for Minas Gerais was approximately USD 701 million, 9.42 percent of the total state budget or about USD 41 per capita.

The states and municipalities can be responsible for specific tax and expenditure functions and for the full management of basic health care for their respective health services. The funds are based on per capita estimates, and administration is based on percentage of population covered rather than number of procedures completed. Programs that are funded in this way include the Basic Care, Basic Pharmaceutical Care, Nutrition, Health Surveillance, and Family Health programs. The HIV/AIDS and malaria programs are considered to be of strategic importance to the nation and therefore receive direct federal support. Municipalities are responsible for registering their HIV/AIDS and malaria patients directly with federal agencies to receive these benefits.

Theoretically, SUS provides free health care to all citizens; however, this promise has become increasingly difficult to keep. The MOH has been exploring the option of motivating the segment of the population with sufficient financial resources to exit the public health system and seek care in the private sector. One of the main challenges of dividing health services in this way is that the quality of services offered, the availability of services, and their respective costs may not be comparable. In 2000, the National Health Insurance Agency (Agência Nacional de Saúde Suplemental) was created (Law 9961/2000) with the mandate to ensure that health insurance programs contribute to national health and development goals, including equity in access and quality. By linking data provided by registered programs with the national health database (DATASUS), it is expected that the agency will also be able to control costs to the public system by preventing double billing of SUS, the private insurer, and/or the patient, and potentially be reimbursed by the private sector for services rendered to those who have a private insurance plan.

The four types of private health plans operating in Brazil are commercial health insurers (e.g., Bradesco, Sul América/Aetna), medical groups or health maintenance organizations (HMOs) (privately owned companies that hire physicians), self-managed plans (*auto-gestão*) (company-owned and -operated plans that provide benefits to employees and family members, or insurance offered by hospitals), and physician cooperatives (physicians are members of the cooperative and share in decision making about how it will operate). HMOs account for the largest share of the private insurance market (Table 6). About one-quarter of the Brazilian population buys private health insurance (IBGE, 1998); of this group, the majority had a private health plan offered by a commercial agency or a business with a self-managed plan. Most of these plans are available to the population in cities where these types of health plans are located. Very few offer any coverage for medications.

**Table 6. Insurance Coverage and Market Share, Brazil, 1998**

Type of Coverage	Population Covered (Millions)	% Total Population	% Share of Market (Rounded)
Health maintenance organizations (HMOs)	17	10	42
Physician cooperatives	10	6	24
Self-managed plan	9	5	22
Commercial insurance	5	3	11
<b>Total</b>	<b>41</b>	<b>24</b>	<b>100</b>

*Source:* Adapted from Alvarez, 1999.

## ***The Pharmaceutical Sector***

### *Pharmaceutical Policy, Laws, and Regulations*

A comprehensive national drug policy (NDP) was published by the Brazilian MOH in 1998, with the explicit purpose of supporting the national health policy and the basic right of all citizens to health care. With the power of a formal policy in place, the MOH was able to enhance, implement, and enforce the several existing pieces of legislation and to fill in the gaps that remained. The NDP provides the guidelines and specifies priorities and responsibilities for all government levels regarding the assurance of access to medicines essential to public health.

A comprehensive listing of all pharmaceutical legislation and regulations may be found on the Web site of the Conselho Federal de Farmácia (CFF) (Federal Pharmacy Council) at [www.cff.org.br](http://www.cff.org.br).

### Essential Drugs

The evolution of the NDP in Brazil is characterized by many starts and stops. Of most immediate relevance, it is important to recognize the passage of Decree 52.471 in 1964; the decree mandated the creation of a public national pharmaceutical industry, consistent with a larger economic policy of import substitution industrialization. One year later, Decree 53.612 was passed; this decree charged that a national formulary be established. In 1975, the formulary became the national essential drugs list (Relação Nacional de Medicamentos Essenciais [RENAME]). Decree 53.612 stipulates that federal public funds should be used to procure only those items on the list, preferably from a national manufacturer. However, this decree was never really enforced.

It was not until 1998, after political support for the NDP was gained, that the RENAME was updated (to include 303 drugs with 545 different presentations) according to WHO guidelines

and selection criteria for establishing an essential drugs list (EDL). The RENAME's fundamental role in guiding procurement was revived, and it took on the added roles of guiding prescribing and dispensing (P.507/GM de 23/4/99). In 2000, a minimum obligatory list of 19 key drugs was formulated for use in the Basic Care Program (P.16/GM de 4/12/00) (Annex B).

Currently, states and municipalities are to consider the RENAME as the list of drugs available through SUS, and they are to develop their own lists using the RENAME as their guide but tempered by epidemiological data. The drugs on the RENAME are selected on the basis of their public health relevance and other basic criteria such as cost, quality, and, increasingly, cost-effectiveness. Recommendations for additions to the RENAME may be made by any interested party through the MOH's Web site. However, formal review (including additions and deletions) is the responsibility of a committee of health professionals (Comissão Técnica e Multidisciplinar de Atualização da Relação Nacional de Medicamentos Essenciais). The EDL for the state of Minas Gerais is presented in Annex B.

In 1999, the MOH passed a regulation (P. 176) that established the criteria for the qualification of municipalities and states to participate in the Pharmaceutical Care Program (Incentivo à Assistência Farmacêutica Básica) as a means to further implement the NDP. Following the overall model for management of health services under SUS, this program allows for the distribution of federal funds to the states and municipalities for the purchase of drugs, on the condition that the states and municipalities provide a plan for implementation of the program and demonstrate sufficient financial and managerial capacity. These plans should be consistent with the overall health goals and programs already in place in the states and municipalities, and should be approved by the corresponding health committees and councils at each level; funding is to be based on per capita estimates.

### Generics and Patents

In 1993, Decree 793 was passed, establishing the first pieces of what was eventually to become a comprehensive policy in support of generic products as a means to lower costs and improve quality of care. This decree addressed several important considerations for the practice of pharmacy. It stipulated that the generic name be clearly listed on the packages of all medicines and that pharmacists be present in all pharmacies, among other things. However, this decree lacked sufficient support for implementation and enforcement.

Two other key pieces of legislation in support of the NDP are the 1997 Patent Law (9279/96) and the 1999 Generics Law (Law 9.787/99). The Brazilian Patent Law is in compliance with most of the requirements of TRIPS ([Agreement on] Trade-Related Aspects of Intellectual Property Rights), including patent protection for pharmaceuticals. The key difference is that the Brazilian legislation stipulates that the holder of a patent must satisfy a "local working" requirement to have full patent protection. If this condition is not fulfilled, the patent is subject to the possibility of the government issuing a compulsory license if the drug is needed to meet a national priority (Bermudez et al., 2000). Perhaps the most significant implication of this is that it allows the Brazilian government to grant compulsory licenses to local manufacturers for generic antiretroviral drugs because it has declared HIV/AIDS a national health priority. The

1999 Generics Law is primarily a cost-control tool; it specifies guidelines and responsibilities related to assuring the quality, safety, and efficacy of generic products and related to bioequivalence.

### Prices

Price controls have been an important part of medicines policy in Brazil. Pharmaceuticals have been subject to price ceilings because they are considered to be of national strategic importance. Price increases have been based on increased production costs but have typically been well above inflation rates, making drug prices a constant public concern. Of specific relevance are the most recent drug price controls introduced by Law 10.213 (March 27, 2001); this law calls for a freeze on drug prices, while stipulating that the freeze will end in December 2002, and allows for indexed increases based on a predetermined formula. It also created the Chamber of Medicines to oversee its implementation.

### Quality Assurance

Support for quality assurance in Minas Gerais was formally mandated in 1998 by Municipal Law 7031/96 after several counterfeit drugs were found on the market. The law requires inspection of facilities that handle medicines, foods, and agricultural products. Drug inspections focus on the whole supply chain, from raw materials and manufacturing to transportation, distribution, and dispensing. As of 2001, there were 40 drug inspectors in the state but only 7 were trained in good manufacturing practices (GMP). This number is considered insufficient, and there is concern that inspectors, once trained in GMP, are easily drawn into the private sector where the remuneration is greater and more secure.

The National Agency for Health Surveillance (Agência Nacional de Vigilância Sanitária [ANVISA]), established in 1991, is the federal agency responsible for inspecting facilities where drugs are handled. Each state of the republic has a corresponding agency (Vigilância Sanitária Estadual [VSE]). All drug facilities (manufacturers, distributors, pharmacies, and drug shops) must register with the VSE. Hospital pharmacies must also register with ANVISA. Inspections of drug shops (*drogarias*) are done at the municipal level, whereas the VSE inspects pharmacies. (Drug shops only sell drug items, while pharmacies may produce them.)

ANVISA inspections are required for registration of a facility and for certification by the Conselho Regional de Farmácia (Regional Pharmacy Council). The inspections include the technical evaluation of the physical plant, personnel, and standard procedures (i.e., whether GMP is used).

The VSE is supposed to inspect all drug manufacturing facilities, one-third of all drug shops, and half of all pharmacies every year. Working conditions are least restrictive for drug shops, for which the only requirement is to have adequate drug storage conditions. In contrast, pharmacies must have security for controlled drugs as well as adequate storage and refrigeration. Depending on the nature of any problem discovered, the VSE may bring in another state department such as

the police. Both drug shops and pharmacies must be owned and managed by a pharmacist, and a pharmacist should be on the premises during operating hours, although the latter condition is often not met, as evidenced in the SEAM survey findings in Minas Gerais (Table 7).

**Table 7. Pharmacies with Pharmacist Present at Time of Interview, Minas Gerais**

Pharmacist Present	Pharmacies	% of Total
Yes	8	38
No	13	62
<b>Total</b>	<b>21</b>	<b>100</b>

Five national laboratories analyze drug products on behalf of ANVISA. The state laboratory (Fundação Ezequiel Dias [FUNED]) does most inspections in Minas Gerais. If FUNED is unable to run the analysis, another lab in Rio de Janeiro (Instituto Nacional de Controle de Qualidade de Saúde) is asked to perform the analysis.

Brazil has a well-organized system for tracking drug quality problems, and legal sanctions are levied and enforced. Complaints about the quality of medicines can be filed by ANVISA, VSE, the pharmaceutical industry, any health facility, or the consumer. The VSE investigates the complaints and, if necessary to track the source of the problem, contacts a counterpart in another state. For example, if a complaint of a contaminated product is filed in Rio Grande do Norte (another state) for a product manufactured in Minas Gerais, the VSE in Minas Gerais will follow up with a physical inspection of the facility and laboratory inspection of the product.

In 1998, ANVISA recorded 166 counterfeit drugs in Brazil. The types of problems encountered were—

- 77 percent contained an active principal drug at the correct strength and from a reputable origin, but the distribution channel was clandestine.
- 13 percent were from other than reputable origins and probably contained no active principal drug.
- 7 percent contained no active principal drug.
- 3 percent contained the active principal drug in a different strength than stated on the label.

According to ANVISA, of these counterfeit products, the three main therapeutic categories represented were analgesics/antipyretics (16 percent), antibacterials (11 percent), and intestinal anthelmintics (7 percent).

In 1998, in the state of Minas Gerais, 30 medications were found to be counterfeits. In comparison, 101 counterfeit drugs were found in the state of Rio de Janeiro for the same period. In large part, the problem in Minas Gerais was due to a single distributor that modified the

packaging of generic products so that they would look like brand-name products. As a result of this finding, the VSE began to emphasize inspection and monitoring of manufacturing and distribution practices.

According to a study by the Health Sciences Faculty of the University of Brasilia (Guerra et al., 2000), of 25 facilities that had complaints filed about them in 1998 in Minas Gerais, 84.6 percent were subject to physical inspection of processes; of these, 95.5 percent failed inspection. Twenty-three of the 25 cases resulted in legal action being taken against the responsible parties. However, despite this fairly high level of enforcement, there are no standard procedures or forms for reporting quality problems. In addition, no mechanism exists to give feedback to the persons affected by the problems. The same study also highlighted the differences among state health surveillance agencies. According to the study, the VSE of Minas Gerais is more formalized and active than its counterparts in São Paulo and Rio de Janeiro.

### *The Market*

#### Private Sector

The pharmaceutical sector in Brazil is quite complex and sophisticated. The Brazilian pharmaceutical market ranked ninth in the world in 2000 and was valued at more than USD 7.4 billion, with 81.8 percent of this value attributed to medicines produced in Brazil (Table 8). Sales of medicines in 2000 were estimated to be USD 5.1 billion. In terms of consumption per capita, Brazil ranks 13th in the world. According to IMS Health, the value of the annual consumption per capita in 1998 was USD 53.75. By 2000, this value had fallen to USD 44.00 per capita, in large part reflecting a severe devaluation of the national currency. Of the estimated USD 27 billion in private expenditures on health, 37 percent was spent on medicines.

**Table 8. Brazil's Pharmaceutical Industry**

	<b>1998</b>	<b>2000</b>
Value of market (in USD billions)	10.31	7.40
Annual per capita consumption (in USD)	53.75	44.00

*Source:* Associação Brasileira da Indústria Farmacêutica (ABIFARMA).

Nationwide, there are 369 manufacturers (306 based in Brazil), 130 drug distributors, and nearly 7,000 wholesalers. As of 2001, there were about 5,200 products (9,200 different presentations) registered with ANVISA. Approximately 80 percent of the market consists of products manufactured locally. Since the passing of the Generics Law in 1999, the number of firms manufacturing generics has been increasing. According to ANVISA, the registration of generics has been increasing exponentially. A Web site is being created jointly by ANVISA and the CFF to allow for public tracking of the registration of generics. To give an idea of the volume increase, sales of generics increased 404 percent between 2000 and 2001, from USD 25 million to USD 126 million (CFF).

There are more than 45,000 pharmacies and drug shops (one outlet for every 3,207 inhabitants) in Brazil (Table 9). Most pharmacies and drug shops are individually owned shops, although there are a few large chains and some owners may own more than one shop. Drug shops are also usually individually owned, but because they sell only prepackaged medicines (they do not make their own products), the requirements for having a pharmacist on duty have been relaxed. In reality, there is rarely a pharmacist on duty at either pharmacies or drug shops.

**Table 9. Structure of the Pharmaceutical Market in Brazil and Minas Gerais, 2001**

Type	Brazil <sup>1</sup>	Minas Gerais <sup>2</sup>
Manufacturers	369	48
Distributors	130*	300**
Wholesalers	7,000	NA
Pharmacies and drug shops	45,000	7,175***

<sup>1</sup>Source: ABIFARMA (www.abifarma.com).

<sup>2</sup>Source: Interview with Conselho Federal de Farmacia; Vigilância Sanitária Estadual, Minas Gerais.

Note: NA = not available

\*Exclusive pharmaceutical distributors.

\*\*Distributors that may also distribute other goods as well as pharmaceuticals.

\*\*\*This figure represents 2,432 pharmacies and 4,743 drug shops.

Another type of drug outlet is called the *posto de medicamentos*. Originally instituted in 1960 (Decree 74170, article 17) as an emergency measure for populations in rural areas where no pharmacy or drug shop was available, it was considered to be a “first-aid” source of drugs like analgesics and antacids. However, it was not until 1993 when Resolution 536 was instituted that the conditions under which *postos de medicamentos* could be licensed were formalized and a list of drugs that could be dispensed safely to the population was established. These outlets are privately owned and operated and are licensed and inspected by the VSE. Owners are not pharmacists and have no formal training in pharmacy practice or dispensing drugs. These shops are considered to be microbusinesses and are therefore exempt from paying taxes, although some shops can be quite large. They are allowed to stock enough simple drug products to cover the needs of 3,500 people for a period of up to six months (although it is widely recognized that many shops exceed the limits on quantity and selection). A *posto de medicamentos* can operate only if it is outside a stated distance from a *drogaria* or pharmacy. Thus a *posto* will lose its license if a drug shop or pharmacy begins operation within the specified vicinity, a fate that awaits all *postos* that are not in the farthest corners of the state. It is not clear how many *postos* are in operation.

The sale of medicines is restricted to authorized licensed facilities. Physicians and clinics have very limited rights with respect to the sale of pharmaceuticals, and many hospitals do not have an outpatient pharmacy. In Minas Gerais, *postos* have formed an association and are attempting to gain wider dispensing functions. Some *postos* have already gained permission to dispense some prescription-only drugs. However, it is difficult to reconcile different laws and codes. For example, in 1993, several provisional acts were enacted that had repercussions for drug sales; one of these was a provision in the Generics Law that formally allows supermarkets and drug shops (where there is no pharmacist) to sell a limited list of nonprescription pharmaceutical

products directly to consumers. Both the sale of medicines in supermarkets and the continued existence of *postos* are viewed by the professional association and ANVISA with unease.

About 80 percent of all drug expenditures in Brazil are out-of-pocket, and 70 percent of all drug sales are of prescription-only drugs. Of the latter, the most common categories are antibiotics (17 percent), analgesics, and vitamins. In Brazil, compared with more developed countries, there is a greater use of antibiotics and analgesic/anti-inflammatory drugs and less use of cardiovascular drugs. Brazil is the world’s largest consumer of amphetamines; approximately 20 million tons are consumed per year. Sales of antidepressants such as Prozac increased 43 percent between 1999 and 2001 (Associação Brasileira da Indústria Farmacêutica [ABIFARMA]).

It is widely recognized that the vast majority of prescription-only drugs are sold without a prescription for self-medication. The MOH is concerned about the prevalence of the practice of self-medication, as it estimates that at least 10 percent of admissions to hospitals in Brazil are because of adverse drug reactions after self-medication.

### Prices

Price controls were used in Brazil until 1992 as a way to protect consumers. Prices were controlled through the public posting of official price ceilings for drugs. Prices were allowed to increase only at a rate below inflation. After 1992, the system changed to what WHO calls “monitored freedom,” in which the pharmaceutical industry volunteers to cooperate with the government to set prices. Prices may be adjusted on a periodic basis by an amount calculated on the basis of the change in the price of the raw materials and other costs. Manufacturers must submit the evidence to justify price adjustments. In March 2001, a new law was passed (Law 10.213) that put a freeze on drug prices until December 2002, allowing for adjustments on the basis of a new index. Clearly, one of Brazil’s most important strategies for controlling prices is through the promotion of a generics industry. Although the price structure varies according to individual state taxes and taxes for transporting items across state lines, a rough breakdown of the price structure for medications is presented in Table 10.

**Table 10. Drug Price Structure, Brazil**

Item	%
Margin (Pharmacy)	25.5–28.4
Distribution	15
Taxes	18–30.5
Freight/warehousing	4

*Sources:* ABIFARMA; interview with Sindicato do Comércio Varejista de Produtos Farmacêuticos, Minas Gerais.

Minas Gerais has 48 medium-sized or small manufacturers. These manufacturers sell their products mostly to other states in the north and northeast of Brazil. About 300 companies distribute drugs in Minas Gerais. Most are located in larger cities such as Juiz de Fora,

Uberlândia, Poços de Caldas, and greater Belo Horizonte (interview with the VSE de Minas Gerais).

### *Public Sector*

In 2001, the Ministry of Health's budget for medicines was 1.57 billion Brazilian reais (BRL), or USD 613.3 million. The public pharmaceutical sector has a system for the manufacture, purchase, and distribution of drugs based on the RENAME and follows the decentralized management scheme involving the federal, state, and municipal levels. Until May 1997, the public pharmaceutical supply system in Brazil was centralized under the federal agency Central de Medicamentos (CEME) (Center for Medical Supplies). CEME, created in 1971, was to complement the existing health insurance system by providing medicines to those too poor to buy them. CEME, which was responsible for both the manufacture and distribution of essential drugs, developed into an ineffective and corrupt agency, and the government was forced to close it in 1997. As a result of CEME's closure, the Brazilian government in 1998 developed a transitional drug supply program, Basic Pharmacy (Farmácia Básica), to supply a kit of essential drugs to municipalities with populations of fewer than 21,000 inhabitants. The Basic Pharmacy Program has continued to evolve rapidly.

A network of 15 official laboratories survived the closing of CEME. These labs are charged not only with inspection and quality assurance responsibilities but also with the manufacture of the most basic items. For example, the official state laboratory in Minas Gerais, FUNED, is responsible for producing the 42 items on that state's EDL. Not all of the laboratories are able to produce all the items in the quantities required, and not all states have a state laboratory; for these reasons, some states contract with private manufacturers to help fulfill requirements.

The Basic Pharmaceutical Care Program (Assistência Farmacêutica Básica) was established in 1999. This program involves three drug supply systems that are managed at the state level by the State Pharmaceutical Care Office (Coordenação de Assistência Farmacêutica [CAF]) of the State Secretariat of Health (SSOH). They are the aforementioned Basic Pharmacy Program, the Federal Mental Health Program (Programa Federal de Saúde Mental), and the Program for Exceptional [high-cost] Drugs (Programa de Medicamentos Excepcionais). Each state is responsible for implementing the program in their jurisdiction, which involves coordination among municipalities. The total budget for the Basic Pharmaceutical Care Program in 2001 was about USD 525 million, nearly 4 percent of the federal health budget, distributed across the various programs, as described in more detail below—

- The Basic Pharmacy Program is a co-funded program in which the MOH sends BRL 1 per inhabitant to the *fundo estadual único* (single state fund). About 13 percent of the total MOH drug budget is spent on this program. The state and municipalities each contribute a minimum of BRL 0.50 per inhabitant to the fund (total of USD 2 per capita). With these funds, CAF arranges the manufacture of the drugs listed on the state EDL. Quantities are based on consumption information sent from the municipal directorates of health via the regional coordinators. Most drugs on the list are manufactured by the official laboratory and sent to the state medical store, usually located nearby. The items are then sent from the state medical store to the municipal medical stores.

For the Basic Pharmacy Program, CAF monitors the single state fund to ensure that municipalities have contributed their BRL 0.50 per inhabitant each trimester. For those municipalities that have not, CAF withholds the distribution of drugs until the contribution is made. According to CAF in Minas Gerais, in the first trimester of 2001, 25 percent of the municipalities had not contributed their quota to the fund and would not receive drugs.

The Full Pharmacy Management Program (Programa Gestão Plena de Farmácia) is a variation of the Basic Pharmacy program that allows the federal and state contributions to be sent directly to municipalities that are accredited by the federal MOH as competent in handling their own drug procurement. Municipalities in this scheme are all medium to large cities with well-developed governments. Only 53 of the 600 municipalities in Minas Gerais participate in the program. These municipalities procure their drugs primarily from the official state and federal drug manufacturers.

- The Program for Exceptional Drugs covers drugs used for serious medical procedures such as renal dialysis and organ transplantation and accounts for about 30 percent of the total drug budget. This program is funded solely by the federal MOH, which sends the funds directly to CAF. CAF purchases the 37 drugs for this program from various sources, including many international companies, and sends them to the regional health coordinators (there are 25 regions in Minas Gerais). Quantities are based on consumption data sent by the regional coordinators to CAF. The regional directorates provide the drugs directly to the patients or to the physician in charge in the district.
- The Federal Mental Health Program is also funded directly and solely by the MOH (but from the Secretary of Health Policy) and is managed in the same way as the Program for Exceptional Drugs except that the drugs are delivered to municipalities through the regional health offices. This program accounts for about 2 percent of the total drug budget.

Other SUS drug supply programs bypass the SSOH and are administered directly between the federal and municipal levels. They are—

- The Strategic Drugs Program (Programa de Medicamentos Estratégicos) for the HIV/AIDS, malaria, tuberculosis, Hansen's disease, leishmaniasis, and diabetes programs where the Directorate of Strategic Drugs of the MOH procures the drugs from the national and private laboratories and has them sent to the state medical store. The Regional Health Office submits requests from the municipalities to CAF, which then gives a distribution plan to the state medical store. The state medical store distributes the drugs directly to the municipal medical stores, which then distribute to the health facilities (or the health facilities may pick up from the medical store). This program accounts for about 52 percent of the total drug budget.
- The Family Health Program (Programa de Saúde da Família) was established and is managed by the Directorate of Family Health of the MOH. Drugs are supplied in kits that

are purchased from private laboratories and distributed directly to municipalities. Each kit is based on the estimated needs of 5,000 inhabitants and on capacity to administer the supplies (there must be a medical team of doctor, nurse, nurse auxiliary, and pharmacist working in the municipality for it to receive a kit). Multiple kits are sent if many teams are working in a municipality.

- The Program for Oncology Drugs has a unique system in which funding is sent by the MOH directly to the hospitals that are responsible for purchasing the drugs for specific patients.

Drug needs for the next trimester are based on the amount of funding available to the respective municipalities in the region for that trimester; for the CAF-managed programs, this information comes either directly from the municipalities or from the Regional Health Office. The federal programs each have a state coordinator who receives consumption information from the municipalities on a trimester basis. This information in turn is sent to the federal program administrator on an annual basis for programmed procurement. Because the SUS programs are administered by separate secretariats within the federal MOH (for example, the Essential Drugs Program falls under the Secretariat of Health Policy and the Strategic Drugs Program falls under the Executive Secretariat), there is some discussion about bringing them under a single administration.

### *Public Sector Drug Supply in Minas Gerais*

Health facilities report that they receive their basic supplies on average about a week after submitting a request (usually in person) to the Regional Health Office or CAF. Eight of the 21 facilities surveyed reported that they receive regular updates on inventory status from CAF. After confirming the request and submitting it to the state medical store (usually located next to the official state laboratory), the order is dispatched to the municipal medical store. The facilities do not have their own transportation, but this was not considered an important problem by the facilities surveyed.

The number of items normally stocked in the health facilities surveyed ranged from 0 to 240 (median of 35). Health facilities were not able to report on the average value of their drug inventories. The lack of standard inventory and fiscal control records is pervasive in the area studied. Only five of the facilities surveyed used any type of record book for inventory control purposes. To determine drug quantities to be purchased, the most common procedures are to review the history of demand and to rely on the “general expertise of professional personnel” (Table 11). Records used to determine order quantities are mostly shelf cards and stock cards. Computer-based reports are used in only 2 of the 21 facilities surveyed (Table 12).

**Table 11. Methods Used to Determine Quantities of Drugs to Purchase, Minas Gerais**

Method	N <sup>1</sup>	% of Total
Analysis of consumption history	10	47.62
Analysis of morbidity data	4	19.05
Comparison of consumption and morbidity data	5	23.81
General expertise of professionals	8	38.10
Scheduling (quotas)	3	14.29
Stock analysis	2	9.52
Demand	1	4.76
Medical prescriptions	1	4.76
Budget determines quantities	1	4.76
No information	4	19.05
Not applicable	4	19.05

<sup>1</sup>N = 21; more than one answer was permitted.

**Table 12. Documents Used to Determine Quantities of Drugs to Purchase, Minas Gerais**

Document	N <sup>1</sup>	%
Stock card	5	23.81
Shelf card	6	28.57
Computer report	2	9.52
Drug checkout log	1	4.76
Daily dispensing/medical prescription	1	4.76
Monthly chart	3	14.29
None	1	4.76
No information	3	14.29
Not applicable	4	19.05

<sup>1</sup>N = 21; more than one answer was permitted.

Purchase decisions are usually made by the facility director. Only two facilities reported that the decisions are made by a committee, although neither included community representation. In the event that CAF cannot fulfill orders (usually because the labs cannot meet the requirements due to production or fiscal limitations) or in case of emergency, facilities may procure drugs directly from the private sector. Usually this would be done through a local purchase based on the best of three price quotes. Facilities may also procure directly from the official laboratories, although none of the facilities in the sample from Minas Gerais reported having procured medicines in this way. Although they may conduct a tender (either international or national), most public sector facilities do not have the capacity to do so.

The state and two regional medical stores that were visited were in good condition and of sufficient size (no overcrowding observed). The areas reserved for drug storage were considered sufficient by most facilities surveyed. Ventilation was also considered to be adequate. However, half of the public health facilities surveyed had no temperature control equipment (three facilities used fans to control the temperature in drug storage areas). For the storage of vaccines and thermo labile products, 12 facilities had cold storage equipment (refrigerators); the temperature was reportedly monitored in eight of these.

Unlike these stores, however, FUNED and the state warehouse appeared to be too small; all shelving space was taken, and additional packaged drugs were stored on pallets on the floor. The warehouse operations seemed to be under control, with good documentation of movement of drugs into and out of the warehouse. The warehouse management system is computerized, and lot numbers and expiration dates of drugs are traceable down to the facility level. The warehouses use the first in, first out (FIFO) order for drug distribution. Vaccines are stored in appropriate cold rooms in the state warehouse and are delivered to the municipalities in cold boxes using refrigerated trucks.

#### Use

The RENAME is supposed to guide not only the procurement but also the prescribing of drugs within SUS. However, as indicated in Table 13, many facilities do not have the RENAME or any other list. Standard treatment guidelines are currently being developed that will support the use of the RENAME. Currently, the few guidelines that exist have been published by different agencies, typically for specific health conditions. The MOH anticipates that there will be improved health outcomes and greater efficiencies with the widespread use of these guidelines.

**Table 13. Essential Drugs Lists Available at Facilities Surveyed (N = 21)**

Essential Drugs Lists	Facilities Reporting Availability	Facilities Reporting Use of List to Guide Prescriptions
National essential drugs list (RENAME)	3	3
State essential drugs list	8	5
Municipal essential drugs list	2	3
Facility's own essential drugs list	8	4
Facility has no essential drugs list	2	NA

Notes: More than one answer, or no answer, was possible. NA = not applicable.

The most frequently used drugs lists are the state's essential drugs list and the facility's own list. They both were mentioned by 8 of the 21 facilities. Only two facilities said they do not have any list. The state EDL is also the reference most frequently used as a prescription guide (by five facilities), followed by the facility's own list, which was mentioned in four cases. When facilities

reported using their own EDLs, the lists include an average of 103 items (from a low of 40 to a high of 315), but this figure may not be correctly reported.

In six of the eight facilities that have their own lists, the decision on what drugs to include is made by one person—usually the director of the county health department, a pharmacist, a physician, or a nurse; in the other two, this decision is made by a professional committee. Lists are not changed regularly in four cases; the lists are changed whenever necessary in two cases, four times a year in one case, and once a year in one case. The most common reasons for adding, removing, or changing items on the list were the demand for drugs and the prescription data. Only 3 of the 21 facilities reported making use of standard treatment guidelines to guide prescriptions.



## **Access to Essential Medicines, Vaccines, and Related Health Commodities**

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The measures of access to essential medicines and medical supplies presented in this report are based on indicators reflecting important dimensions of access that were identified at the joint WHO-MSH meeting on defining and measuring access, held December 11–13, 2000, in Ferney-Voltaire, France.

Results are presented for Minas Gerais whenever possible, and compared with national data.

### **Geographic Accessibility**

#### *1. Percentage of households more than 20 kilometers away from a health facility and/or pharmacy*

Data for this indicator is not readily available for Brazil. Related data to address this dimension of access was obtained through secondary sources, primarily the health supplement to the 1998 National Household Survey (Pesquisa Nacional por Amostra de Domicílios [PNAD]) and the 1999 Public Health Survey (Pesquisa de Assistência Médico-Sanitária [PAMS]) conducted by the IBGE.

By way of review, the total number of health facilities in Brazil in 1999 was 56,133 (one facility for every 3,028 inhabitants), a 13 percent increase over 1992 (Table 14). The number of public facilities increased 22 percent. In Minas Gerais, there were 7,143 health facilities, 18 percent located in the metropolitan region of the capital city of Belo Horizonte. As mentioned earlier, the SUS network has continued to expand and includes virtually every municipality of the country to some degree or another. This growth has been particularly supported by the recent effort to expand the Family Health Program (supported by medicines kits), which targets poor and remote populations. Although both health facilities and private drug outlets tend to be concentrated in urban centers, the distribution of drug outlets is wider, facilitated by a strong distribution system.

**Table 14. Number of Inhabitants per Facility, Minas Gerais and Brazil (1999)**

<b>Factor</b>	<b>Minas Gerais</b>	<b>Brazil</b>
Inhabitants per health facility (all types)	2,380	3,028
Inhabitants per pharmacy	2,370	3,207
Rate of health service utilization per 100 persons	NA	12.7

Sources: IBGE, 1999; Conselho Regional Farmácia (interview).

Note: NA = not available.

According to the PNAD of 1998 (IBGE, 1998), one-third of the Brazilian population does not regularly use any health facility. The rate of health services utilization was estimated to be 12.7 per 100 persons, with a slightly higher than average rate for high-income patients. In order of importance, the services that are used regularly are listed in Table 15.

**Table 15. Ranking of Health Services by Rate of Regular Use, Brazil (1998)**

Type of Service	% of Population Reporting Regular Use of Service
Health post or health center	41.8
Hospital outpatient clinic	21.5
Private physician	19.7
Private clinic	8.3
Emergency service	4.8
Pharmacy	2.2
Outpatient service of a business or labor union	1.5
Community health worker	0.1

Source: IBGE, 1998.

Of those who did not seek care during the two-week period prior to the interview for the PNAD study, 96 percent reported that they did not need it. However, of the other 4 percent who did not seek care, 17 percent (0.59 percent of the population) reported that they did not do so because the services were too distant or because they lacked access to transportation. This finding suggests that the physical distribution of services in general is not a significant barrier to care for most Brazilians and that barriers to access are likely to be of another nature.

## 2. Average number of operating hours per day, by type of facility

The complementary indicator to physical access to services is whether the facility is operating when people need it. According to the 1998 PNAD, only about one-third of one percent (0.34 percent) of the respondents surveyed indicated that the reason they did not seek medical attention when it was needed was that the operating hours of the facility were not convenient.

The results from the survey for the present study are presented in Table 16. The operating hours for the NGO facilities were the longest, followed by those of private facilities. However, it is important to point out that most of these facilities have no outpatient dispensary. Therefore, although patients may have access to a health care professional at these facilities, as outpatients they would be required to fill their prescriptions at a private pharmacy. In this respect, the private pharmacy operating hours are much more favorable than the hours of the public sector dispensary. Indeed, private pharmacies are required to participate in a rotation to ensure that one pharmacy in a given area is open (or on call), even during the least attractive times from the commercial perspective.

**Table 16. Operating Hours by Type of Facility, Minas Gerais**

Factor	Public Facility (N = 21)	Private Facility (N = 15)	NGO/ Phil. (N = 20)	Private Pharmacy (N = 21)
Average number of operating hours per day	4.5	20.7	17.5	12.1
Average number of operating hours—weekday	11.3	10.1	20.9	14.2
Average number of operating hours—weekend	2.3	17.4	20.7	10.9
Facilities open on Saturday or Sunday	2	10	19	13 <sup>1</sup>

Source: Strategies for Enhancing Access to Medicines survey, 1998.

Note: NGO = nongovernmental organization, Phil. = philanthropic.

<sup>1</sup>Plus five that participate in a rotation of operating hours.

## Availability of Medicines and Information

### 1. Percentage of a set of unexpired tracer items in stock

The amount of inventory is a key indicator of the functioning of a supply system. Two indicators are used together to measure inventory status: one evaluates the presence of tracer items at the time of data collection, and the other evaluates the tendency to be out of stock over a period of time.

For the analysis, 21 tracer items were selected. The items were selected from the RENAME for 2000 and the corresponding list for Minas Gerais, the *Relação Estadual de Medicamentos* (REME) for 2001. Together, these lists are supposed to guide the prescription, dispensing, and stock management of medications in the state of Minas Gerais. Two physicians (one from the MSH team, another from *Núcleo de Estudos em Saúde Coletiva e Nutrição* [NESCON]), and two pharmacists (one from MSH and the other from the *Escola Nacional de Saúde Pública* [National School of Public Health]/*Fundação Oswaldo Cruz*) selected the tracer items. Isoniazid and rifampicin combination and the measles vaccine were included because they are on the list of so-called “strategic medicines” sponsored by a federal program, and male condoms were included because they are on the list of items supplied by the Family Health Program. Information on the availability of the 21 tracer items was collected at public medical stores, health centers, and hospitals; private hospitals and clinics; hospitals and clinics of NGOs and philanthropic organizations; and private pharmacies.

The results for the first indicator (the availability of tracer items at the time of data collection) are presented in Table 17. The average availability of all tracer items is less than 50 percent in the public, private, and NGO services. This result is not surprising for the private and NGO sector facilities because most of these outpatient facilities do not regularly stock medicines as part of a dispensary service. Patients who receive prescriptions from these facilities are generally expected to have them filled at a public dispensary or private pharmacy. The relatively high level of availability of the tracer items in private pharmacies suggests that these facilities are a reliable

source for public health medicines. Scores for some items—such as measles vaccine, isoniazid/rifampicin, and the 250 mg presentation of metronidazole (500 mg is more common)—are very low because these items are provided through public health campaigns and not usually sold in private pharmacies. If these items are excluded from the analysis, overall availability in private pharmacies increases to 88 percent, with an average of 16.7 items from the tracer list available.

The most alarming result is the lack of availability of items in the public facilities. This deficiency, of similar proportion in the warehouses and the facilities, is a sign of a supply system that is not functioning well, and the reasons for this require further investigation. One implication of this lack of stock is that the patients, who have the right to essential medicines free of charge from public facilities, are obliged to purchase items they need at the private pharmacies. Some likely contributing factors to the low levels of availability include the lack of trained personnel, the lack of an information system to track stock levels or consumption, and insufficient financing. There is a growing dissatisfaction with the current per capita funding that penalizes poorer municipalities, and a task force has been appointed to reexamine the formulas used to determine contributions based on equity and need.

Table 17. Availability of Tracer Items (N = 21 Items)

	Public Medical Stores % (N = 16)	Public Health Facilities % (N = 14)	NGO/Phil. Facilities % (N = 14)	Private Facilities % (N = 7)	Private Pharmacies % (N = 21)
Acetylsalicylic acid tablet 100 mg	44	43	77	71	100
Amoxicillin capsule 500 mg	13	36	46	43	100
Amoxicillin suspension 50 mg/ml	31	36	69	14	100
Benzylpenicillin benzathine ampule 1,200,000 IU	50	43	69	71	90
Captopril tablet 25 mg	56	57	54	71	95
Cimetidine tablet 200 mg	63	57	54	57	100
Diazepam tablet 10 mg	69	50	54	100	90
Erythromycin suspension 25 mg/ml	69	57	17	0	76
Erythromycin tablet 500 mg*	38	50	15	14	100
Glibenclamide tablet 5 mg	25	21	46	29	81
Hydrochlorothiazide tablet 50 mg	50	57	54	71	100
Isoniazid + Rifampicin capsule 200 + 300 mg	31	29	0	0	5
Male condom**	33	23	15	0	90
Measles vaccine**	36	36	15	0	0
Mebendazole suspension 20 mg/ml	44	50	31	14	95
Metronidazole tablet 250 mg	38	50	15	14	24
Oral rehydration salts (envelope)	81	71	54	14	90
Paracetamol 100 mg/ml*	25	36	23	57	86
Propranolol tablet 40 mg	56	50	54	57	100
Salbutamol solution 2 mg/5 ml*	75	71	62	43	90
Sulfamethoxazole + Trimethoprim tablet 400 + 80 mg	75	71	69	57	90
<b>Average number of tracer items available</b>	<b>10</b>	<b>10</b>	<b>9</b>	<b>8</b>	<b>16</b>
<b>Percent (average) availability of the set of tracer items</b>	<b>47</b>	<b>47</b>	<b>41</b>	<b>38</b>	<b>78</b>

Note: NGO = nongovernmental organization, Phil. = philanthropic.

\*Presentation in the REME is different from that in the RENAME.

\*\*Does not appear in the RENAME, but is part of the Family Health Program.

2. *Percentage time out of stock for a set of tracer items*

To calculate this indicator, it is necessary to verify, by means of registers or other records, the incidence of any stock-outs and the length of time of any stock-out for the 12 months prior to the study (in this case April 2000 to April 2001). This indicator expresses the proportion of days out of stock for the year. Together with the first indicator, it allows for the determination of the probability of the occurrence of a stock-out over a longer period of time.

Unfortunately, it was not possible to calculate this indicator for the state of Minas Gerais because of the lack of sufficient information about inventory and stock-keeping in the public and private sectors. At all levels, the management information system for drug supply is precarious at best; most often, one does not exist. A comparison of the two regional health offices is illustrative of how different even the same type of facility can be in terms of record-keeping practices. The Regional Health Office in Diamantina has a systematic system for both keeping and providing information to the facilities it supplies, whereas the one in Montes Claros has no such system but rather manages stocks on an ad hoc basis. It is very likely that the lack of medicines observed is largely the result of the absence or nonfunctioning of any information system, a situation that has important implications for financial control and global planning for health services at all levels.

3. *Percentage of medicines prescribed that are also dispensed*

The treatment of a patient is compromised when he or she is not able to obtain the medications needed. Ideally, all prescribed medicines should be dispensed. However, the correct interpretation of the indicator still requires an understanding of the health system in which medicines are prescribed and dispensed. If the system uses (or should use) a list of medicines to guide the prescribing, dispensing, and stock management of medicines, and if medicines are available free of charge to patients, as is the case of the public health system in Brazil (SUS), there should be high correlation between what is prescribed and what is dispensed. Lack of stock is a common reason for lack of dispensing under these conditions, although sometimes prescribers will adapt their prescriptions to match what items are in stock. When the patient is obliged to cover the entire or even partial cost of treatment, the prescribed medications may not be dispensed because the patient cannot afford them.

To calculate this indicator, information that links prescriptions with dispensing is needed. This information may be obtained from a single record maintained at the dispensary or by matching a patient record with a dispensing record. For the facilities in the sample for this study, the availability of information within each sector, and between each sector, varied considerably. For example, only 8 of the 20 public facilities maintain prescribing and dispensing registers, 10 reported having only prescription records, and 2 reported not having any records at all for either prescribing or dispensing. The few private facilities (4/15) and NGO/philanthropic facilities (6/17) that dispensed medicines appear to maintain better information. It was possible to evaluate the occurrence of dispensing for only 37 percent of the prescribed medications in the public sector, 56.6 percent of those prescribed in the private sector, and 53.6 percent of those in the NGO/philanthropic sector. The results, presented in Table 18, may be unreliable given the small sample (e.g., dispensing records were obtained for only 37 percent of the prescriptions in the public sector). On the other hand, data obtained through patient exit interviews in 18 of the

public sector facilities is more reliable and indicates a higher percentage of prescriptions that are not dispensed. Of the 299 medications prescribed to the patients who were interviewed, 218 (72.9 percent) were not dispensed (Table 19). The interviewees reported that they intended to fill 41 percent of these prescriptions in another SUS pharmacy and expected to purchase another 42 percent in a private pharmacy. These results are consistent with the indicator on the availability of tracer items in stock.

**Table 18. Dispensing of Prescribed Medicines, According to Records in Facilities**

Indicator	Type of Facility		
	Public (N = 20)	Private (N = 15)	NGO/Phil. (N = 17)
Total number of prescribed medications evaluated	1,033	691	974
Prescribed medicines for which there is dispensing information	383	391	522
Number of prescribed medicines that were dispensed	276	192	427
Percentage of prescribed medicines that were dispensed	72.1	49.1	81.8

Note: NGO = nongovernmental organization; Phil. = philanthropic.

**Table 19. Obtaining Prescribed Medication, per Patient Exit Interviews at Public Facilities**

Did you receive the medications prescribed?	N	%
Yes, all of them	77	25.8
Yes, some of them	4	1.3
No, none of them	218	72.9
<b>Total</b>	<b>299</b>	<b>100</b>

#### 4. Percentage of facilities with a reliable or “valid” source of information about medications

The underlying assumption behind this indicator is that the possibility of rational prescribing increases if prescribers have access to “valid” information about medicines. Although the criteria defining “valid” were not specified at the MSH-WHO meeting in Ferney-Voltaire, types of information about drugs can be classified according to their origin and purpose. Traditional pharmacopeias, for example, offer information about product formulation and little or no therapeutic information. More modern pharmacopeias contain a lot more therapeutic information in addition to the pharmacologic information (e.g., *Martindale: The Extra Pharmacopoeia*). Pharmacologic texts (e.g., *Goodman and Gilman’s The Pharmacological Basis of Therapeutics*, *Remington’s Pharmaceutical Sciences*) and medical compendia contain minimal information about product formulation and a lot of information about factors related to adequate or appropriate prescribing. Medication dictionaries, such as the *Dicionário de Especialidades Farmacêuticas* (DEF), are generally financed by the pharmaceutical industry and generally contain the information published in the package inserts that are distributed with the medications; these publications are rarely subject to critical review by a legal or professional authority.

Eleven of 21 public facilities investigated reported that they have access to at least one source of information about medications (Table 20), with the medication dictionary DEF being the most cited (six facilities). More important, however, is that 10 of the 21 reported not having any source of information about drugs at the time of the survey, revealing that lack of any type of drug information is a problem in the public sector. This is in sharp contrast with the variety of information sources available in private pharmacies, although the most common source of information was still the DEF (Table 21).

**Table 20. Availability of Sources of Information about Medications, Minas Gerais**

Indicator	Type of Facility			
	Public (N = 21)	Private (N = 13)	NGO/Phil. (N = 20)	Private Pharmacy (N = 21)
No source of information about medication is available	10	3	3	0
Some source of information about medication is available	11	10	17	21

Note: NGO = nongovernmental organization, Phil. = philanthropic.

**Table 21. Sources of Information Available in Private Pharmacies, Minas Gerais**

Source	Number (N = 21)	%
RENAME	0	0.00
Standard treatment guidelines	1	4.76
Pharmacopeia	3	14.29
Pharmacology textbook	7	33.33
DEF	20	95.24
List of generic/brand names	14	66.67
Other	7	33.33

Note: RENAME = Relação Nacional de Medicamentos Essenciais, DEF = *Dicionário de Especialidades Farmacêuticas*.

The Internet was cited as a source of information by some private and NGO facilities. The use of the Internet in Brazil has increased greatly in recent years, and with the support of a federal program to expand access, this trend can be expected to continue. There are dozens of Web sites for virtual pharmacies and doctor's offices (see, for example, [www.guiafarma.com.br](http://www.guiafarma.com.br), which lists services for the city of Rio de Janeiro by zip code). Other Web-based informational resources aimed at professionals include the *Centro Brasileiro de Informação sobre Medicamentos* (CEBRIM) sponsored by the CFF. The Zanini-Oga Group sponsors [www.farmacia.med.br](http://www.farmacia.med.br), which posts, among other things, the *Dictionary of Generic Medicines* and targets both consumers and practitioners.

5. *Percentage of the population that has access to a reliable or “valid” source of information about medicines*

This indicator complements the previous one because it also focuses on the availability of information. The methodology of the present study did not permit data to be collected for this indicator, nor was any study found that addressed this question directly for Brazil.

The sources of information that could be used by the population include several that were also mentioned by the facilities. Package inserts, either individual or compiled and published in the DEF; magazines; and newspapers are among the most easily accessible sources. Self-medication has long been recognized as a significant problem in Brazil, and the powerful pharmaceutical industry is often believed to be the prime instigator because of its propaganda in the mass media (Loyola, 1984; Temporão, 1986; Barros, 1995; Bonfim, 1999). According to the patient exit interviews at public facilities that were conducted as part of the present study in Minas Gerais, physicians are an important source of basic information. In 122 (86 percent) of the 142 interviews, physicians were reported as responsible for providing the name of the medication to the patient. The physician provided information about the therapeutic use of the medication in 88.3 percent of the cases. Nineteen of the 21 private pharmacies studied reported that they offer some information about medications to their clients, even though the presence of a pharmacist is not guaranteed. Of the 21 private pharmacies, 13 had no pharmacist present at the time of the interview, and six of these facilities did not even have a pharmacist on their staff.

One source of information that is gaining importance over time is the Internet. The various virtual pharmacies and doctor’s offices on the Internet offer information about medications and their prices, and some present articles about health (treatment and prevention) in addition to information about other products. A recognized authority rarely evaluates this information, and few of these companies have adopted a code of ethics to guide the presentation of drug information and use of information by users (consumers) who visit the Web site. Largely for this reason, the State Secretariat of Health in Minas Gerais has sought to guide consumers by linking its official site with various “legitimate” sources of health and health-related information.

Several commercial and public service-oriented Web sites target patient groups with specific conditions. Two important public service Web sites are those of the MOH and the State Secretariat of Health. The latter contains a large amount of information on health services and the performance of the health sector. Nonetheless, although the federal government has begun to promote the expansion of access to the Internet to low-income residents and residents of geographically isolated areas through innovative social responsibility programs, it is important to keep in mind that in Minas Gerais, as in much of Brazil, large segments of the population still do not have access to the Internet.

## ***Affordability***

### *1. Average percentage difference between the most and least expensive prices for a set of tracer items*

This indicator describes the market from the perspective of the patient as purchaser. The interpretation of this indicator depends on the context of the market. It is possible that in a context of little or no competition, the difference between prices is less than what might be observed in a context that promotes competition. A larger difference might be expected in a market that is highly competitive when generics are allowed to compete with brand-name products. The national drug policy in Brazil stimulates competition by promoting the production, prescription, and distribution of generics through the Generics Law (Law 9.787/99) of 1999. Generics are being heavily promoted through educational campaigns aimed at both professionals and laypersons. The result is that today there is a strong and growing generics market in Brazil.

Under the SUS, all public health services, including drugs, are free to patients. Therefore, this indicator was calculated only for the private pharmacies. The minimum and maximum prices and the proportion of the difference between these are presented in Table 22. The last column presents the average percentage difference between the most expensive and least expensive prices for those pharmacies where both pieces of information were obtained for the product. In general, the difference between the prices appears to be great, suggesting that patients have purchase options in terms of prices. The results in Table 23 suggest that the customer would do well to compare different pharmacies to obtain better prices, as there is a 259 percent average difference between the lowest prices offered for tracer items. The MOH position and public sentiment is that SUS patients should not be asked to comparison shop to obtain the best prices for essential drugs.

The least expensive price charged to patients for each tracer item was also compared with the recommended retail price listed in the *ABC Farma* for May 2001 (Table 24). The *ABC Farma* is a catalog of products published by the Brazilian Pharmaceutical Retail Association (*Associação Brasileira do Comércio Farmacêutico*) and is widely distributed to pharmacies in Brazil. Nine items on the tracer list were not listed in the *ABC Farma*, most likely because the manufacturers of these products are not very large. In general, the prices charged by the pharmacies were 132 percent lower than those suggested by the *ABC Farma*. Since the area where the study was carried out is relatively impoverished, it is reasonable to expect that the prices offered by the pharmacies there would be lower than the suggested retail price.

**Table 22. Average percentage difference between the least and most expensive prices charged for tracer items in private pharmacies (in BRL)**

Generic Name	Facilities with Item in Stock (N = 21)	Unit Price(BRL)			
		Min. (a)	Max. (b)	Max./Min. (b/a)	Avg. % diff. (No. of Pairs)
Acetylsalicylic acid tablet 100 mg	21	0.0400	0.1500	3.75	87 (13)
Amoxicillin capsule 500 mg	21	0.4533	1.8667	4.12	75 (18)
Amoxicillin suspension 50 mg/ml	21	0.0513	0.1863	3.63	97 (18)
Benzylpenicillin benzathine bottle/ampule 1,200,000 IU	19	2.3000	7.0000	3.04	45 (6)
Captopril tablet 25 mg	20	0.1563	1.3370	8.56	187 (17)
Cimetidine tablet 200 mg	21	0.1625	0.6910	4.25	121(11)
Diazepam tablet 10 mg	19	0.1445	0.4400	3.04	129 (14)
Erythromycin oral 25 mg/ml	16	0.0450	0.2126	4.72	130 (10)
Erythromycin tablet 500 mg	21	0.6667	2.9320	4.40	59 (13)
Glibenclamide tablet 5 mg	17	0.1000	0.3585	3.59	95 (14)
Hydrochlorothiazide tablet 50 mg	21	0.0805	0.2175	2.70	75 (20)
Male condom	19	0.2667	1.0000	3.75	103 (18)
Mebendazole suspension 20 mg/ml	20	0.0533	0.2067	3.88	66 (16)
Metronidazole tablet 250 mg	5	0.2100	0.4435	2.11	69 (1)
Oral rehydration salts (envelope)	19	0.1875	3.4000	18.13	253 (15)
Paracetamol solution 100 mg/ml	18	0.1300	0.5713	4.39	144 (12)
Propranolol tablet 40 mg	21	0.0580	0.1670	2.88	44 (6)
Salbutamol solution 2 mg/5 ml, ampule 120 ml	19	0.0223	0.0545	2.44	60 (16)
Sulfamethoxazol + Trimethoprim tablet 400 + 80 mg	19	0.1960	1.1600	5.92	157 (15)
<b>% average difference of all items</b>					<b>105</b>

Note: Min. = minimum, Max. = maximum, Avg. = average, diff. = difference.

Table 23. Lowest Prices to Customers of Private Pharmacies, Minas Gerais

Generic Name	Facilities with Item in Stock (N = 21)	Lowest Unit Price (BRL)			
		Avg. Lowest Price	Min.	Max.	% Sifference
Acetylsalicyclic acid tablet 100 mg	21	0.0649	0.0400	0.1200	200
Amoxicillin capsule 500 mg	21	0.8553	0.4533	1.8667	312
Amoxicillin suspension 50 mg/ml	20	0.1044	0.0513	0.2318	352
Benzylpenicillin benzathine bottle/ampule 1,200,000 IU	16	5.3569	2.3000	6.9700	203
Captopril tablet 25 mg	20	0.3799	0.1563	0.9375	500
Cimetidine tablet 200 mg	21	0.2842	0.1625	0.3663	125
Diazepam tablet 10 mg	20	0.2396	0.1445	0.4400	204
Erythromycin oral 25 mg/ml	16	0.1067	0.0450	0.1667	270
Erythromycin tablet 500 mg	21	1.3812	0.6667	1.8550	178
Glibenclamide tablet 5 mg	18	0.1446	0.1000	0.2400	140
Hydrochlorothiazide tablet 50 mg	21	0.1166	0.0805	0.1565	94
Male condom	20	0.3832	0.2667	0.6667	150
Mebendazole suspension 20 mg/ml	20	0.1000	0.0533	0.1300	144
Metronidazole tablet 250 mg	5	0.3472	0.2100	0.4435	111
Oral rehydration salts (envelope)	20	0.7763	0.1600	2.0000	1150
Paracetamol solution 100 mg/ml	15	0.2702	0.1300	0.5120	294
Propranolol tablet 40 mg	21	0.0900	0.0580	0.1650	184
Salbutamol solution 2 mg/5 ml, ampule 120 ml	19	0.0290	0.0223	0.0542	143
Sulfamethoxazol + Trimethoprim tablet 400 + 80 mg	17	0.3472	0.1960	0.5175	164
<b>% average difference of all items</b>					<b>259</b>

Note: Min. = minimum, Max. = maximum, Avg. = average.

**Table 24. Unit Price Comparison of Lowest Sample Price (Minas Gerais) with the Suggested Retail Price in ABC Farma (BRL)**

Generic Name	Commercial Name (Manufacturer)	Lowest Sample Price <sup>1</sup> (a)	ABC Farma (May 2001) (b)	ABC Farma Price (b/a)
Acetylsalicylic acid tablet 100 mg	AAS infantil (Sanofi-Synthelabo)	0.0400	0.10	2.5
Amoxicillin capsule 500 mg	Amoxicilina (Eurofarma) <sup>2</sup>	0.4533	0.42	0.9
Amoxicillin suspension 50 mg/ml	Amoxicilina (Eurofarma) <sup>2</sup>	0.0513	0.04	0.7
Benzylpenicillin benzathine 1,200,000 IU	Penicilina G Benzatina (Ariston)	2.3000	nc	nc
Captopril tablet 25 mg	Capton (Royton)	0.1563	nc	nc
Cimetidine tablet 200 mg	Cimetidine (MedQuímica)	0.1625	nc	nc
Diazepam tablet 10 mg	Dienpax (Sanofi-Synthelabo)	0.1445	0.21	1.4
Erythromycin oral suspension 25 mg/ml	Erimicina (Globo)	0.0700	nc	nc
Erythromycin tablet 500 mg	Eritromed (Medquímica)	0.6667	nc	nc
Glibenclamide tablet 5 mg	Apex (Davidson)	0.1000	nc	nc
Hydrochlorothiazide tablet 50 mg	Hydrochlorotiazide (Teuto)	0.0805	0.11	1.4
Male condom	Prudence (Karex)	0.2667	nc	nc
Mebendazole oral suspension 20 mg/ml	Trotil (Globo)	0.0533	nc	nc
Metronidazole tablet 250 mg <sup>3</sup>	Metronidazole (Teuto)	0.2100	0.31	1.5
Oral rehydration salts – packets	Baby Drax (União Química)	0.1875	1.93	10.3
Paracetamol oral solution 40 mg/ml	Tylaflex (MedQuímica)	0.1300	nc	nc
Propranolol tablet 40 mg	Propranolol (Biosintética)	0.0580	0.07	1.2
Salbutamol oral solution 2 mg/5 ml, 120 ml	Salbutamol (Teuto) <sup>2</sup>	0.0223	0.04	1.6
Sulfamethoxazole + Trimethoprim tablet 400 + 80 mg	Sulfamethoxazole + Trimethoprim (EMS) <sup>2</sup>	0.1960	0.27	1.4

Note: nc = not included in the ABC Farma.

<sup>1</sup>Price in reals of a comparison unit (tablet, packet, bottle, bottle-vial, condom).

<sup>2</sup>Generic drug.

<sup>3</sup>Questionnaire considered availability of 500 mg presentation, which is not commonly found in market.

## 2. *Average percentage difference between international prices and public sector prices for a set of tracer items*

This well-known indicator is used to evaluate how efficient tender systems are for procurement. The assumption is that resources are always limited so greater efficiencies should be sought. The motives for reducing expenditures and minimizing costs include being able to use the money saved to provide services to more people or to expand existing services.

Procurement is a particularly complex area of drug management. Prudent procurement involves several factors, including the availability of up-to-date information about prices, a reliable supply

of products, processes that make optimum use of resources (human and financial), and a system that both the buyer and the purchaser trust.

Three comparisons were conducted. The first involved comparing the prices obtained for the drugs on the tracer list by public medical stores and pharmacies in Minas Gerais that conducted tenders using the median international tender prices listed in the *International Drug Price Indicator Guide* (IDPIG), published by MSH. The second analysis compared prices obtained by facilities in the sample from Minas Gerais with those published by the Ministry of Health in the *National Price Register* (*Registro Nacional de Preços de Medicamentos e Correlatos*). The *National Price Register* reflects prices quoted to the federal government through competitive tenders and is meant to be used as a reference for prices. All organizations linked to the MOH should purchase their drugs and medical supplies from suppliers that have agreed to sell items for the posted prices or less. It is prohibited to buy items on the register for prices higher than the posted prices. The third compared the international prices with the prices in the *National Price Register*.

Perhaps not surprisingly, given the strong national pharmaceutical industry, the prices obtained by the medical stores and public pharmacies surveyed were comparable to the international prices (Table 25). Five (35.7 percent) of the 14 prices obtained by these facilities were higher than the international prices, but on average prices were 4 percent less than the international prices. The prices that the medical stores and public pharmacies paid were higher than the *National Price Register* prices for 8 (72.7 percent) of the 11 items. On average, prices paid were 19 percent higher than the register prices. Glibenclamide prices have a significant difference (191 percent), suggesting a problem with the purchase of this item. In contrast, on average the prices obtained for the purchase of amoxicillin (suspension, 50 mg/ml) by the medical stores and public pharmacies were very favorable—96 percent less than the price listed in the *National Price Register*.

The prices in the *National Price Register* compare favorably to those listed in the IDPIG. Of the nine medications compared, only five had prices higher than those in the IDPIG. On average, register prices are 4 percent lower than the international prices. The drugs with prices very much above the average are amoxicillin (500 mg capsules) (125 percent) and glibenclamide (5 mg tablets) (160 percent). The prices of amoxicillin are slightly lower than the international tender prices, with an average difference of 4 percent.

Table 25. Price Comparison (USD)

	Sample of Stores/Public Pharmacies (a)	IDPIG 2000 (b)	MOH Price Register <sup>2</sup> (c)	% Diff. Sample/ MSH (a)-(b)/ (b)	% Diff. Sample/ MOH (a)-(c)/ (c)	% Diff. MSH/ MOH (c)-(b)/ (b)
Acetylsalicylic acid tablet 100 mg	0.0050	0.0040	0.0045	25	11	12
Amoxicillin capsule 500 mg	0.0950	0.0422	0.1067	125	-11	153
Amoxicillin suspension 50 mg/ml – ml	0.0065	NA	0.1788	NA	-96	NA
Benzylpenicillin benzathine ampule 1,200,000 IU	0.4355	NA	0.3313	NA	31	NA
Captopril tablet 25 mg	0.0103	0.0213	0.0110	-52	-7	-48
Cimetidine tablet 200 mg	0.0128	0.0325	NA	-61	NA	NA
Diazepam tablet 10 mg	0.0073	0.0097	0.0060	-25	22	-38
Erythromycin suspension 25 mg/ml	0.0103	NA	NA	NA	NA	NA
Erythromycin tablet 500 mg	0.0558	0.0920	NA	-39	NA	NA
Glibenclamide tablet 5 mg	0.0172	0.0066	0.0059	160	191	-10
Hydrochlorothiazide tablet 50 mg	0.0057	NA	NA	NA	NA	NA
Isoniazid + Rifampicin capsule 200 + 300 mg	0.0544	NA	NA	NA	NA	NA
Male condom	NA	0.1190	NA	NA	NA	NA
Measles vaccine	0.3888	0.4261	NA	-9	NA	NA
Mebendazole suspension 20 mg/ml	0.0063	0.0315	NA	-80	NA	NA
Metronidazole tablet 250 mg	0.0118	0.0187	0.0115	-37	2	-38
Oral rehydration salts (envelope)	0.1428	0.1419	0.1115	1	28	-21
Paracetamol solution 100 mg/ml	0.0139	NA	NA	NA	NA	NA
Propranolol tablet 40 mg	0.0067	0.0099	0.0052	-32	29	-48
Salbutamol solution 2 mg/5 ml, 120 ml	0.0025	0.0046	NA	-46	NA	NA
Sulfamethoxazol + Trimethoprim tablet 400 + 80 mg	0.0204	0.0176	0.0188	16	9	7
<b>Average</b>				<b>-4</b>	<b>19</b>	<b>-4</b>

Note: NA = not available, Diff. = difference.

<sup>1</sup>USD 1.00 = BRL 2.3148.

<sup>2</sup>Ministry of Health, *National Price Register* ([www.saude.gov.br/RegPreço](http://www.saude.gov.br/RegPreço)).

### 3. Number of days that a salaried worker needs to work in order to pay for a standard treatment of a tracer condition

This indicator aims to capture the concept of affordability from the perspective of the patient. It is a variation of one that was introduced at the MSH-WHO Ferney-Voltaire conference. The original indicator was based on the salary of the lowest paid government worker. The reason for

using the civil servant for this index is the high probability of the existence of reliable published information about the salaries of civil servants. With this type of information, one can create an index of relative values that can be compared over time both in the same country and with those obtained in other countries.

Instead of government salaries, in Brazil, as in other countries, the convention of minimum salaries is used. Minimum salaries are based on the concept of a basic basket of requirements (food and other items) for an individual. The minimum salary in Brazil in May 2001 was BRL 180 per month or BRL 5.81 per day. According to the National Household Survey (PNAD) of 1997, 15 percent of the Brazilian population received at least one minimum salary; this was true for a slightly higher percentage (19 percent) of the population in Minas Gerais. According to the PNAD of 1998, 16 percent of all Brazilians 10 years old or more received at least one minimum salary, but in the southeast region, where Minas Gerais is located, the figure was lower, at 11 percent, suggesting a change in the economic situation of the people in Minas Gerais.

When the 1998 PNAD was conducted, one of the main reasons why 1.13 percent of the population, the poorest, did not seek medical attention when needed was the lack of funds. While this may not seem like a large segment of the population, it is important to realize that with the implementation of SUS, the national government aimed to eliminate the financial barrier to health services. However, as the indicators suggest, access to medicines may still represent a problem, with some patients paying out of pocket at private pharmacies to obtain needed drugs.

In contrast with free care through SUS, in the private pharmacies, the median price charged for a tablet of co-trimoxazole (80/400 mg) is BRL 0.475. To treat a five-year-old child for an acute respiratory infection, according to the standards of the World Health Organization's guidelines for the *Integrated Management of Childhood Illness* (2000), the cost would be BRL 4.75, or 0.82 percent of the daily wage received by a person earning one minimum salary.

#### 4. *Percentage of the population covered by a risk-sharing, prepayment health insurance scheme*

The interest in health insurance schemes comes, in large part, from the attempt to control costs that are rising because of the incorporation of new technologies and more sophisticated and higher quality services and medicines. The correct interpretation of this indicator requires an understanding of the health financing system in place.

As of 2001, approximately 25 percent of the population of Minas Gerais had some type of private health insurance. About 60 percent of these plans are financed completely (13 percent) or partially (46 percent) by the employer, and 40 percent are covered by UNIMED, a nonprofit cooperative with affiliates throughout Brazil. Most plans offer a package of services that includes physician visits, medical examinations, and hospitalization. Not all plans include a drug component, although UNIMED is exploring this avenue.

Theoretically, SUS covers the basic health needs, including medications, of each citizen. The medicines on the national essential drugs list, the RENAME, are to be provided free of charge. Theoretically, no Brazilian needs private health insurance. However, when options exist in the

supply of services, when not all services are perceived as being the same (given personal preferences of patients), and when there is a perception that the quality of services differ, the segment of the population with greater purchasing power will seek out their options and preferences.

If the premise that resources are always limited and costs are increasing is accepted, the question of how to finance the health system to at least maintain a certain level of care becomes a question of access. Besides keeping costs down (through more prudent purchasing, for example), one option for increasing efficiencies in the public sector is to motivate the segment of the population with sufficient financial resources to exit the public health system and seek care in the private sector.

According to the 1998 PNAD, 38.7 million Brazilians (24.5 percent) were covered by at least one private health plan. Of these, the majority (75 percent) had a private health plan offered by a commercial agency or business with a self-managed plan. Therefore, it is not surprising that coverage was greater in urban areas, where most jobs and businesses are located. One of the main challenges of implementing this shift away from SUS for some patients is in the balance among the quality, the supply, and cost of services. The Ministry of Health is grappling with these issues as it attempts to improve the image of public health services while it attempts to control costs.

### ***Acceptability/Satisfaction***

The acceptability/satisfaction dimension of access approximates the criteria of responsiveness used to describe the performance of health services in the *World Health Report* (WHO, 2000:31). Responsiveness refers to how aspects of the health system relate to the expectations of the public. This concept has two components, one that focuses on respect (respect for human dignity, confidentiality, and patient autonomy) and another that addresses issues of client orientation (punctuality, cleanliness, space, access to social support, and possibility of provider choice). Using these measures, the Brazilian health system was rated as above the standard for two elements: access to a social support network and confidentiality. However, for the other aspects, the rating was lower than the established standard.

The information for the following indicators was generally not available. However, some approximation to the indicators was achieved.

1. *Number of medicines on the national essential drugs list (RENAME) that are among the best-selling medicines in the private sector*

The value of the Brazilian pharmaceutical market in 2000 was USD 7.48 billion, with nearly 82 percent of this value attributed to medications produced in Brazil (<http://www.abiquif.org.br>). According to IMS Health, the value of Brazil's annual drug consumption per capita in 1998 was USD 53.75. By 2000, this value had fallen to USD 44 per capita, in large part reflecting a severe devaluation of the national currency. About 70 percent of drug sales are of prescription drugs, many of which are actually purchased without prescriptions. Of these, the most common items

sold are antibiotics (17 percent). A list of the most commonly sold items for 1999 is presented in Table 26. Diclofenac, which is not listed on the RENAME, appears in both first and fourth place under different brand names and represents USD 189.9 million in sales for 1999. Only 5 of the 10 most commonly sold prescription items are listed on the RENAME.

**Table 26. Ten Top-Selling Drugs in Brazil (1999)**

Brand Name	Generic Name	Sales (USD Million)	Listed on the RENAME (2000)
Cataflam	Diclofenac	120.8	
Keflex	Cefalexin	87.6	✓
Capoten	Captopril	76.8	✓
Voltaren	Diclofenac	69.1	
Amoxil	Amoxicillin	66.6	✓
Tylenol	Paracetamol	63.1	✓
Renitec	Enalapril maleate	58.2	
Novalgina	Dypirone	55.9	✓
Lexotam	Bromazepam	55.0	
Dorflex	Orfenadrina/dypirone	41.1	

Source: Ministry of Health, *Relação Nacional de Medicamentos Essenciais 2000*.

## 2. *Satisfaction with the results of the last visit to a public health facility*

The methodology used for the present study did not permit data collection on this indicator for the region studied. However, the 1998 PNAD did address patient satisfaction with services received by those who received care during the two weeks prior to the study. According to the PNAD, most Brazilian patients evaluated the care they received in the facilities that they normally use as being very good. Only 2.4 percent of the patient visits were evaluated as poor or very poor. Unfortunately, it is not possible to determine from this data the reasons why patients were not satisfied, nor is it possible to determine if any segment of the population tends to be less satisfied or which services were associated with the scores, although the services are most likely to be those affiliated with SUS (Table 27).

**Table 27. Types of Services Normally Used in Brazil**

Type of Service Normally Used	% Population That Utilized Service
Public health center	41.78
Hospital outpatient	21.54
Private health service	19.69
Emergency	4.77
Pharmacy	2.17
Company or union health service	1.49
Community health agent	0.12
Other	0.13

Source: IBGE, 1998.

## ***Quality of Products and Services***

### *1. Percentage of tracer medicines that fail quality testing*

As discussed in an earlier section of this report, Brazil has a health surveillance program that links the national and state systems. The program is capable of following up on complaints and applying sanctions. However, it lacks a formal system for reporting problems and providing feedback on the outcome of investigations of product or service quality. In addition, there is little consistency between the various state agencies not only in their ability to carry out inspections but also in their ability to levy and enforce sanctions. However, it is worth noting that ANVISA has begun to implement a set of standard indicators to address these limitations.

For the purposes of this study, 64 samples were taken of eight different drugs (amoxicillin, captopril, co-trimoxazole, hydrochlorothiazide, mebendazole, metronidazole, paracetamol, and isoniazid/rifampicin) from the three categories of facilities. Of these, 13.6 percent of the samples from public facilities were found to be substandard, 10 percent from NGO/philanthropic facilities, and 9.1 percent from private pharmacies. About 10 percent of the samples failed assay, disintegration, or dissolution tests (Table 28), consistent with findings reported by ANVISA for 1998.

**Table 28. Quality of Drug Products, Minas Gerais, 2001**

Number of drugs sampled	8
Number of samples tested	64
% samples that were substandard*	
Public facilities	13.6
NGO/Philanthropic facilities	10.0
Private retail outlets	9.1
% samples failing assay test	10.9
% samples failing disintegration test**	10.0
% samples failing dissolution test**	9.1

\*Drugs were not evenly represented in the samples.

\*\*Either disintegration time or dissolution time was determined, not both.

*2. Existence of a national essential drugs list and standard treatment guidelines published within the past five years*

In 2000, the Ministry of Health revised and published the national essential drugs list, *Relação Nacional de Medicamentos Essenciais*, following WHO guidelines. The previous list was published in 1993. In principle, this list aims to guide prescribing and dispensing as well as the supply of medicines in the country. Each state and municipality has the responsibility to develop its own lists based on the RENAME.

RENAME 2000 includes 321 medicines with various presentations and dosage forms. The list is organized alphabetically and by pharmacologic group. It does not include standard treatment guidelines or any other therapeutic information about the medicines listed. Standard treatment guidelines are currently being developed.

*3. Percentage of facilities with a copy of the RENAME 2000*

Of the 78 facilities surveyed, 48 (62 percent) reported having a list of essential medicines available (Table 29). Some of these included lists prepared by the facility. Although these lists should be based on the RENAME 2000, this was not confirmed. The most commonly available lists were the state list (REME) and facility lists. Only three facilities, all from the public sector, had a copy of the RENAME 2000. Only two public sector facilities did not have any list available. As mentioned previously, one of the most commonly used references is the DEF, which, while containing valuable package insert information, cannot be considered to be unbiased.

**Table 29. Facilities with an Essential Drugs List Available, Minas Gerais**

Type of Facility	N	National List (RENAME)	State List (REME)	Municipal List	Facility List	Other	None
Private pharmacies	21	0	0	0	0	0	21
Public facilities	21	3	8	2	8	0	2
Private facilities	15	0	0	0	9	0	6
NGO/philanthropic facilities	21	0	0	0	16	2	3

#### 4. Percentage of treatments that conform to standard treatment guidelines

It was not possible to calculate this indicator because no standard treatment guidelines exist for primary care in Brazil, although various guidelines do exist for the treatment of particular conditions, such as HIV/AIDS and leprosy. Nonetheless, it was possible to do a simple analysis of the quality of prescriptions. Thirty patient encounters were reviewed in each of the clinical facilities visited, for a total of 1,400 prescriptions. The results for the prescribing indicators that were calculated are presented in Table 30. Although the rate of prescribing by generic name is the highest for the public sector, it may be considered to be actually very low since theoretically only generic names are to be used when prescribing, per the national policy. The low rate of prescribing drugs that are on the RENAME is similarly a cause for concern, suggesting the need for closer review to determine what items tend to be prescribed off the list and why. If the reasons for this are legitimate, the question must be raised as to the need to revise the list. If the reasons are not legitimate, then the issue becomes one of practitioner behavior change.

**Table 30. Selected Prescribing Indicators, Minas Gerais**

Prescribing Indicator	Type of Facility			
	Public	NGO/ Phil.	Private	Pharmacies
Average number of drugs prescribed per encounter	1.8	2.3	1.8	1.8
% drugs prescribed by generic name	65	36	26	NA
% prescribed drugs that are on RENAME	65	62	49	NA
% encounters where antibiotics were prescribed	18	25	15	37
% encounters where vitamins and tonics were prescribed	0	2	0	NA
% encounters where metamizole was prescribed	10	27	15	NA

Note: Phil. = philanthropic, NA = not available.

Simulated patients were sent to pharmacies and drug shops to obtain information about the quality of the services provided. During the simulation, a person (the data collector or another person trained by the data collector) entered the chosen pharmacy, described the condition of a six-year-old child who had flu-like symptoms and fever, and asked the person at the counter

(salesperson or pharmacist) for guidance on what to do. The types of medications that were recommended included antibiotics (37.5 percent), flu and cold symptom remedies (28.1 percent), analgesics (21.9 percent), and anti-inflammatory medications (3.1 percent). In terms of rational drug use, cold medicines that have certain active ingredients should not be administered to children because of the potential for adverse reactions (such as Reye’s syndrome due to acetylsalicylic acid); also, antibiotics should not be used for nonbacterial infections and should not be dispensed without a physician’s prescription. In addition, combination fixed-dose products are not recommended, and phenylpropranolamine, which is an anti-flu product, was taken off the market in Brazil in 2000.

5. *Percentage of patients who know how to take their medicines*

To gain an understanding of what patients know about the medicines they are prescribed, exit interviews were conducted with 178 persons as they exited the 18 public health clinics and hospital outpatient services surveyed (a total of 315 medicines were prescribed). Patients were asked about the medicines they were prescribed and what they were told about the purpose of the medicine, how much to take, and how long to take it. They were also asked who gave them this information. Patients were told the name of the medication 59.7 percent of the time and were told its purpose 79.5 percent of the time. What the patients reported and what was actually written on their prescriptions did not agree for 11.7 percent of the medicines.

To learn about information that is offered in retail drug outlets (pharmacies), simulated patients were asked to recall what they were told by the person who attended them. In 42 percent of the cases, the patients were told how to take the medicines that were sold to them, but only 5.3 and 15.8 percent were informed about potential adverse reactions and other precautions, respectively. Only 36.8 percent of the patients were instructed to take the fictional six-year-old child to a physician (Table 31).

**Table 31. Information Provided by Pharmacy Staff to 19 Simulated Patients**

Survey Question	Yes	%
Did the staff explain how to take the medication?	8	42.1
Did the staff warn you of any problems that the medicine might cause?	1	5.3
Did the staff give you any suggestions or information about how to treat a child with fever?	3	15.8
Did the staff recommend that you take the child to see a physician?	7	36.8

**Access Indicators Summary**

The following chart shows the collective conclusion of a discussion among representatives of the State Health Department, the MOH, and MSH about assessing the identified access gaps.

**Access to Essential Medicines, Vaccines, and Related Health Commodities**

<b>INDICATOR</b>				
<b>SECTOR</b>	<b>Accessibility</b>	<b>Availability</b>	<b>Affordability</b>	<b>Quality</b>
<b>Brazil in General</b>	Generally good geographic coverage for the distribution of facilities and retail outlets but less coverage in rural and remote areas	Sophisticated marketplace in terms of selection	Serious problem; drug prices outside reach of large percentage of population	Some problems with drug quality; extreme difficulties with quality of service
<b>Ministry of Health</b>	Covers around 85% of population, main source of care for 42% of the population; limited hours of operation; not many outlets in remote/rural areas	Poor availability of drugs, largely due to limitations of distribution system and lack of funding; limited management capacity of municipal staff	In principle, drugs are free to the public for public health needs; however, significant out-of-pocket expenditures still occur among poor	Established federal and state EDLs that are not well disseminated; no standard treatment guidelines; prescribing and dispensing practices weak
<b>Private for Profit</b>	Becoming more accessible to some populations; ambulatory services do not normally stock medicines	Do not normally stock medicines for ambulatory/outpatient services	Do not normally stock medicines for ambulatory/outpatient services	Overall, drug product quality comparable to public sector
<b>Private Not-for-Profit</b>	Becoming more accessible to some populations; ambulatory services do not normally stock medicines	Do not normally stock medicines for ambulatory/outpatient services	Do not normally stock medicines for ambulatory/outpatient services	Overall, drug product quality comparable to public sector
<b>Retail Drug Outlets</b>	Very well distributed; private pharmacies and drug shops reported as being most common source of care for only 2% of population, but are a primary source of medications, both prescribed and over the counter; long hours of operation	Good availability of most essential drugs	Drug outlets demonstrate strategic pricing and flexibility	Overall, drug product quality comparable to if not better than public sector; pharmacies and drug shops are dispensing drugs without prescriptions; prescribing/dispensing practices comparable to public sector



### Strategy Formulation Principles

The proposed intervention in Brazil is based on the findings and principles discussed in the previous sections. The partnership between the public and private sector in providing pharmacy service that is proposed assumes the following—

- Selection of the items to be delivered through the system will continue to be the responsibility of the public sector. The list of the medicines (generic and brand name) will be defined by the Ministry of Health, the State Secretariat of Health, and the Municipal Health Secretariat, in conjunction with their corresponding health councils.
- The production and distribution of items will be carried out by the private sector. The purchase of the items on the selected list will be through the qualified manufacturers and distributors according to the *National Price Register*.
- Purchasing will continue to be centralized by the MOH. Distribution will be decentralized, with vendors selected by the municipalities through competitive bidding.
- The drugs distributed through this system will be packaged according to MOH specifications, with a label that stipulates that the sale of the items is not permitted.
- Prescribing will be done in the public sector. The municipal manager will define the maximum quantity needed of medicines and their distribution according to service utilization and epidemiologic data.
- Dispensing will be shared in a complementary fashion between the public and private sectors. Dispensing will be done by private sector pharmacists for patients enrolled in SUS and being treated at an SUS facility. Dispensing will be free to SUS patients upon presentation of an SUS prescription.
- Accreditation, monitoring, and evaluation of the system will be the responsibility of the public sector. The municipal manager will identify the pharmacies that will be accredited, following the technical and legal criteria to be established. These criteria will address requirements for access and quality of services that will best complement SUS services.
- Monitoring and evaluation will be conducted by means of information sent by the pharmacies to the existing SUS information system (DATASUS), and auditing will be conducted by microregional and state administrative offices. Private pharmacies will provide monthly reports with the number of procedures completed and prescriptions filled. Reports will include patient and prescriber information as well as detailed prescription information.
- Priority will be given to those regions with the greatest geographic access problems.

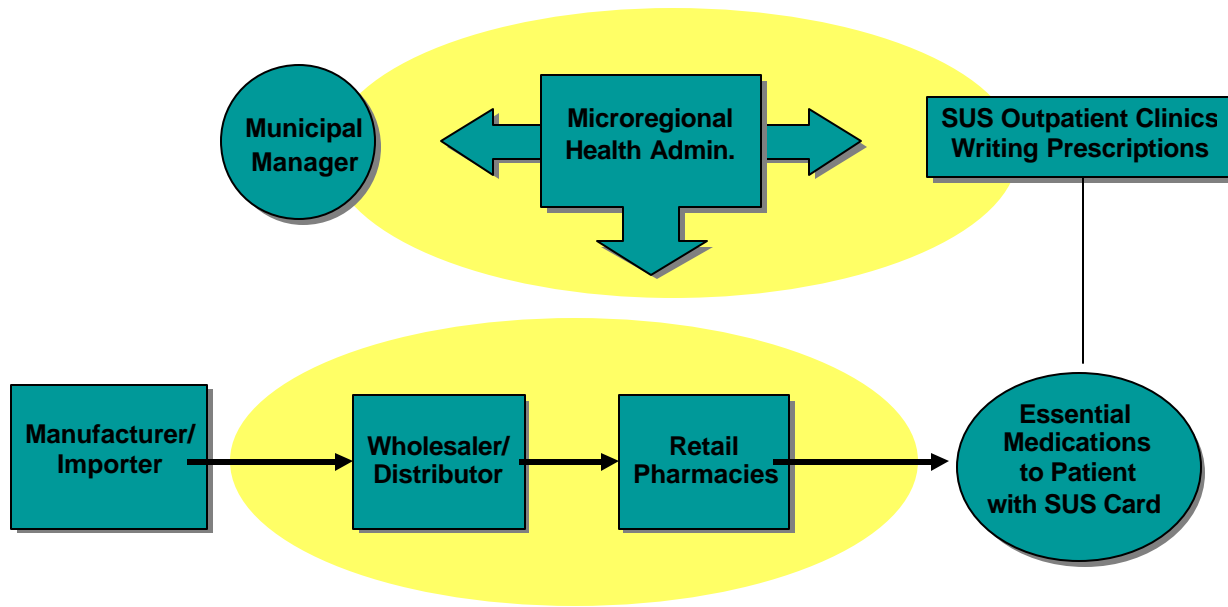


Figure 1. Proposed strategy.

## Expected Impact on Access Gaps

The proposed intervention involves establishing contractual relationships between SUS facilities and private pharmacies and manufacturers for the provision of essential medicines to SUS patients through pharmacies. Three major areas can be addressed by this intervention—availability, geographic accessibility, and quality.

### *Availability*

The Constitution of Brazil guarantees free drugs to SUS patients. If they are paying for the drugs at a private pharmacy because of a lack of availability (for the reasons mentioned previously) at the municipal level, accrediting existing pharmacies to dispense these items, in a way that is complementary to SUS, is a viable solution. Municipalities will be under more scrutiny and pressure to utilize their scarce funds more prudently.

### *Geographic Accessibility*

Patients will have increased accessibility because private pharmacies are open longer hours and because there is wider distribution of retail outlets. Patients needing to refill medications for chronic illnesses in particular will benefit by being able to obtain refills at a local pharmacy rather than having to return to the health center.

## **Quality**

Quality of products and services can be improved. The contractual requirements with SUS will put more pressure on the private sector to be vigilant about the quality of the products they sell and services they provide. The planned improvements of the reporting system of ANVISA will further support this.

Another dimension of quality that will be enhanced is the quality of the information that patients and consumers receive from their health care providers and pharmacies. This will contribute to the improved use of prescribed drugs, particularly patient compliance, an aspect of drug use that, while not specifically addressed in this research, is a significant problem in Brazil.

## **Strengths of the Proposed Intervention**

One of the most important recent developments in health sector reform and management is the passage of NOAS-SUS 01, an operations norm that mandates the identification of local solutions for local problems and that places less emphasis on political boundaries between municipalities in favor of more natural alliances between municipalities, villages, and towns. For the many municipalities that lack the staff with required drug management skills, contracting health services to a local pharmacy would be a welcome alternative to providing care themselves.

Among the advantages of using private pharmacies for this proposed system is that SUS patients will not have to pay for their essential drugs and pharmacies will not have to absorb the costs for patients who do not pay for the drugs they receive. The proposed contractual arrangement, a reimbursement scheme, allows for more reliable payment. Pharmacies will also gain market advantage by being certified as a provider of guaranteed product quality and professional services. Certification should lead to increased clientele and an opportunity to increase the types of services provided by the pharmacy (e.g., patient counseling, medication use monitoring).

Another potential strength is that SUS is currently implementing a national, integrated, computerized management information system. The national health “smart card” (Cartão SUS) is currently being tested and will be implemented by late 2001. The Cartão SUS will permit the monitoring of patient health-seeking behavior within SUS and treatments received. It will also permit the cross-check of management information with clinical information. This system will help prevent duplication of services and fraud.

## **Potential Constraints of the Proposed Intervention**

Perhaps the biggest weakness of the proposed project comes from the fact that the reorganization of the pharmacy services according to the national drug policy is only beginning. It is necessary to strengthen the management capacity of the health system as a whole because the demand for services will increase with the implementation of the proposed project.

As with any change, some resistance from the status quo is to be expected. Therefore, at the municipal level, there will be a need to make a special effort to educate managers about the benefits of the changes, as well as to ensure that the system of checks and balances that are in place already (through the various health councils and committees) are also included in the process.

## The Role of SEAM

The approach presented in this report has been elaborated in consultation with the Ministry of Health on the basis of knowledge of local conditions and considering the results of a survey of pharmacies in two mesoregions of Minas Gerais state (Norte de Minas and Jequitinhonha). The proposal is a pilot project whose main objective is to create and demonstrate a sustainable and replicable solution for increasing access to public sector medications. It aims to address the following dimensions of access—

1. Availability (referring to physical presence of medications and information about them in the pharmacies)
2. Hours of service (number of hours the facility is open on weekdays and weekends)
3. Management skills (a distal determinant affecting numerous dimensions of access), including the provision and use of information in management practice
4. Quality of medications (addressing determinants of quality at different points in the supply chain)

One of the greatest impediments to the provision of drugs through SUS, and to the functioning of the public health system as a whole, is the low level of management skills. Any partnership involving the use of private sector distribution channels under public sector supervision would need a significant improvement in management skills and abilities throughout SUS, especially in departments that deal with pharmaceuticals. The improvement of management capacities would have simultaneous impact on many dimensions of access and would greatly improve the effectiveness and sustainability of improvements over the long term. Such improvement would be reinforced by the availability of information that is of practical and immediate use in daily management practice. SEAM could contribute to the development of these skills, working with the MOH to adapt existing training materials and programs to the Brazilian reality, develop training capacity, and provide other direct technical assistance related to the development of basic drug management tools.

The assessment results from Minas Gerais indicate that quality of medications is another dimension of access that has the potential for improvement. Roughly 10 percent of the samples failed one of the assay, disintegration, or dissolution tests. What makes this dimension attractive as a potential target for intervention is that in addition to an identified problem, the administrative machinery to address it already exists in SUS and only needs to be strengthened and focused on specific targets. ANVISA was recently created at the national level for quality

control of drugs, among other tasks. Although not yet at an optimal level of functionality, ANVISA is an agency with widespread representation at different levels of government throughout all regions of the country. Training of human resources and specific direction of efforts toward private sector manufacturers, distributors, and dispensers would have a tangible effect on improving this vital dimension of access.

By identifying those aspects of access that have significant potential for improvement, and by using existing channels and administrative structures, when feasible, to bring about such improvement, the chances of success and the impact are maximized and the resources and efforts required minimized. MSH will contribute to the following activities in collaboration with local counterparts in the MOH—

- Establish plan and primary support structure for drug supply chain
- Develop selection and accreditation criteria and corresponding management information systems
- Select and prepare private pharmacies
- Organize drug production and distribution
- Adapt and develop auditing procedures for drug supply chain from distributor to patient
- Develop prescription and dispensing guidelines and information, and train human resources to use them
- Develop management guidelines and information, and train human resources to use them
- Initiate and expand function of drug supply chain
- Develop and initiate drug supply chain monitoring and evaluation program
- Adapt and develop product quality control mechanisms

The project's duration is four years, divided into a two-year pre-pilot and a two-year pilot phase. At the end of this period, the proposed drug dispensing scheme should have been tested and proven to be effective and feasible, and should be ready for dissemination nationwide.

The project management team initially starts with three full-time members supported by SEAM, with support by the State Secretariat of Health, as well as other MSH technical staff. Ideally, the SSOH would also make two or three members of its own staff available full-time to work as members of the team. The SSOH members should be recruited from professionals with experience in health administration and/or supply chain management. They should also have significant experience and familiarity with conditions in the interior of Minas Gerais. Some of them may come from present or former staff of the SSOH, or other organs such as the Regional Pharmacy Council. Professionals with solid experience in auditing or quality control would be

useful members of the team. The number of members contracted by SEAM would increase according to the number of clinics and pharmacies involved in the project and according to the volume of other tasks. In the second year, the number of members recruited by SEAM would increase to four, and in the pilot phase (Years 3 and 4) to six (see Annex C for a list of members who assisted with this assessment). Project activities will involve a significant volume of auditing and quality control, tasks that already are carried out by SUS but that need to increase in volume. Financial support should be provided with the explicit understanding that the SSOH is the organ ultimately responsible for these personnel and laboratory expenses, and that it will have to shoulder a constantly increasing portion until it fully finances them.

The selection of microregions and municipalities where the intervention will take place should be carefully considered. The preliminary survey carried out in Minas Gerais took place in two mesoregions called Norte de Minas and Jequitinhonha, which between the two of them have 12 microregions. These are probably the best places to begin the project because they have serious problems of access and because there is baseline data available on them from the survey. At the outset of the project, these 12 microregions should be examined by the project management team together with the SSOH and MSH. Four or five microregions should be chosen on the basis of epidemiologic criteria and the political receptivity to the proposed intervention. The epidemiologic criteria should be examined to identify those areas with greatest need; criteria could include life expectancy and incidence or mortality of certain diseases such as tuberculosis (which is very strongly correlated with poverty) and other diseases that are directly targeted by medications included in the project (which possibly includes hypertension and diabetes). The aim should be to identify those microregions that would experience the greatest positive impact from increased access to certain medications. In addition, great care should be taken to ensure that the political situation is truly favorable to the interventions proposed by the project, as the lack of this factor could potentially render any other advantages irrelevant.

Once the regions are identified, a systematic study of all municipalities should be carried out to identify the existence of pharmacies with minimum standards to fulfill project needs. This study should involve visits to the locations and consultation with local authorities and pharmacy owners (see Annex D for a list of key persons interviewed for this assessment). Subsequently, areas (municipalities, towns, or villages) could be identified where a complex could be formed that would consist of an SUS health clinic and one or two private pharmacies with minimum standards and the possibility to serve the clinic's patients. It is essential that an objective rating scale be created so that the evaluation and identification of the best locations can be as effective and impartial as possible. Every effort should be made to involve many different stakeholders in this analysis and decision making to minimize the influence of self-interest in the selection of locations.

During the first two years, in the pre-pilot phase, a total of 20 complexes are to be formed in the two mesoregions chosen. Once the pilot phase starts, during Years 3 and 4, 20 new complexes will be established in each of the five major regions of Brazil, including the southeast where Minas Gerais is located. The selection of these areas will follow the same objective criteria as used in the pre-pilot phase.

Similarly, the criteria for the qualification and accreditation of pharmacies should be established and rigidly enforced. This is especially important since in the small towns of the interior, pharmacy owners often have close relations to the mayor and other municipal authorities, and disinterested decision making is not necessarily the norm. The performance of each pharmacy should be checked with the Regional Pharmacy Council, and those that do not meet minimum established criteria should not be included in the project in any way. This calculation is also vital to the success of the project because, being the last link, inadequately prepared pharmacies could destroy much of the benefit of an otherwise effective supply chain.

To more adequately validate and demonstrate the impact of the intervention, in addition to the areas chosen for the project, a similar number of areas and localities should be chosen as “controls.” The controls should be in areas of geographic proximity to the project areas and have very similar conditions in terms of the functioning of SUS, living and social conditions, and other factors. They might even be chosen from the same two mesoregions where the intervention is implemented. There should be enough distance, however, that the residents of the control areas do not have any real access to the private pharmacies. One of the major benefits of a controlled study is that the effect of the numerous trends affecting health and access to drugs can be identified and isolated. Controls will facilitate the evaluation of cost-effectiveness of the program, so results would be dramatically more illustrative of the true impact achieved. The two sets of communities should have comparable costs for the provision of drugs, receive fairly similar human resource training, have similar political environments, and have reasonably uniform public demand for drugs. Most important, however, is that the intervention and the control sets of communities have a similar response to extraneous factors that influence access to drugs and health in general. Factors extraneous to the intervention may include decentralization of SUS, specific programs of disease control, and the effectiveness of municipal government. By carefully selecting control locations that have conditions very similar to the intervention locations, the chances of uniformity in extraneous factors are maximized.

Periodic monitoring and surveys allow the impact of the intervention to be assessed. The indicators used have to take into consideration the stated objectives of the project, the dimensions of access targeted, and the original indicators used in the preliminary survey. Also, the use of both proximal and distal indicators is suggested to give a broader understanding of the mechanisms involved in the impact on access. These indicators must be selected after careful discussion and analysis; however, as preliminary suggestions, the following should be considered—

- Percentage of patients who manage to consult a physician without unreasonable delay and get a prescription for a required medication
- Percentage of patients with prescribed medications dispensed (totally and partially)
- Proportion of medications received at SUS clinics and in accredited private pharmacies
- Reasons why patients do not receive prescribed medications (lack of availability, distance from pharmacy, closure of facility, etc.)

- Percentage of patients who desire information on their medications during the act of dispensing (by category of information)
- Percentage of patients who receive adequate orientation and information when medicines are prescribed and dispensed
- Hours of service of pharmacies (weekdays and weekends)
- Availability of each medication to be provided in private pharmacies
- Percentage of pharmacies that are compliant with criteria of the Regional Pharmacy Council, and number of closures if any
- Various indicators of patient satisfaction with the service or services that are prescribed and dispensed
- Various indicators of fraud at different points on the supply chain
- Various indicators of quality control such as percentage of medications from each pharmacy that fail assays, disintegration, and dissolution tests
- Number of SUS administrative personnel trained in management skills
- Qualitative evaluation of management performance of SUS personnel
- Epidemiologic parameters (prevalence, incidence, mortality) of disease targeted by list of medications, such as tuberculosis and hypertension

The establishment of quality control procedures for the project intervention can rely on a structure of surveillance already established and functioning in Minas Gerais. The project could have an important role in identifying gaps and providing technical assistance in the needed areas. One option suggested, for example, is the implementation of a TLC (thin-layer chromatography) testing methodology for first-tier testing of drugs, which is less expensive and easier to run because it requires less maintenance than the more complicated HPLC (high-performance liquid chromatography). It would also allow more quality-control coverage with approximately the same personnel and resources.

## References

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- ABIFARMA (Associação Brasileira da Indústria Farmacêutica). [www.abifarma.com](http://www.abifarma.com).
- Almeida, C. M., C. Travassos, S. Porto, and T. W. F. Baptista. 1999. *A Reforma Sanitária Brasileira: Em Busca da Equidade*. Research in Public Health, Technical Report. Washington, DC: Pan American Health Organization.
- Alvarez, Isabel. 1999. *21st Century Challenges Facing the Brazilian Health Sector*. Report on the 1998 Roundtable held in São Paulo, Brazil. La Jolla, CA: Institute of the Americas.
- Andrade, M., and P. Lisboa. 2001. Mortalidade nos Estados do Rio de Janeiro, São Paulo e Minas Gerais. *Estudos Econômicos* 31, no. 1: 5–56.
- Barros, José Augusto Cabral de. 1995. *Propaganda de Medicamentos: Atentado à Saúde?* São Paulo, Brasil: Hucitec/SOBRAVIME.
- Bermudez, Jorge A. Z., Ruther Epsztejn, Maria Auxiliadora Oliveira, and Lia Hasenclever. 2000. *The WTO TRIPS Agreement and Patent Protection in Brazil: Recent Changes and Implications for Local Productions and Access to Medicines*. Rio de Janeiro: FIOCRUZ/ENSP.
- Bomfin, Jose Ruben de Alcântara. 1999. A Mercadização de Produtos Farmacêuticos e a Inação Governamental no Brasil. In *Medicamentos e a Reforma do Setor Saúde*. São Paulo, Brazil: Hucitec/SOBRAVIME.
- Conselho Federal de Farmácia (Federal Pharmacy Council). [www.cff.org.br](http://www.cff.org.br).
- Guerra, August Jr., Suzanila Sanches Silva, and Ulysses Rodrigues de Castro. 2000. *Study of Counterfeit Drugs in Brazil*. Brasília: University of Brasilia, School of Health Sciences, Department of Collective Health.
- Instituto Brasileira de Geografia e Estatística (IBGE). 1998. Pesquisa Nacional por Amostra de Domicílios (PNAD). Suplemento. *Acesso e Utilização de Serviços de Saúde*. [www.ibge.gov.br/home/estatistica/população](http://www.ibge.gov.br/home/estatistica/população).
- . 1999. Pesquisa Nacional de Assistência Médica Sanitária (PAMS). Brasília. [www.ibge.gov.br/home/estatistica/população](http://www.ibge.gov.br/home/estatistica/população).
- Instituto de Desenvolvimento Industrial de Minas Gerais (INDI). [www.indi.mg.gov.br](http://www.indi.mg.gov.br).
- Instituto de Pesquisa Econômica Aplicada (IPEA). 2002. *Nota do IPEA sobre o Relatório de Desenvolvimento Humano*. 23 Julho 2002. [www.ipea.gov.br](http://www.ipea.gov.br).
- Landim, Leilah, Neide Beres, Regina List, and Lester M. Salamon. 1999. Brazil. In *Global Civil Society: Dimensions of the Nonprofit Sector*, edited by Lester M. Salamon, Helmut K. Anheier,

Regina List, Stefan Toepler, S. Wojciech Sokolowski, and Associates. Baltimore, MD: University of Johns Hopkins Center for Civil Society Studies.

Loyola, Maria Andrea. 1984. *Médicos e Curandeiros: Conflito Social e Saúde*. São Paulo, Brazil: DIFEL, S.A.

DATASUS. Ministério da Saúde. Secretaria Executiva. [www.assistenciafarmaceutica.org.br](http://www.assistenciafarmaceutica.org.br).

———. Secretaria de Políticas de Saúde. 1999. Política Nacional de Medicamentos. Brasília: Ministério de Saúde.

———. Secretaria de Políticas de Saúde. Gerência de Assistência Farmacêutica. 2000. *Relação Nacional de Medicamentos Essenciais (RENAME)*. Ministério da Saúde, Secretaria de Políticas de Saúde.

Temporão, José Gomes. 1986. *A Propaganda de Medicamentos e o Mito da Saúde*. Rio de Janeiro: Edições Graal.

United Nations Development Program (UNDP). 1998. *Human Development Report 1998*. New York: Oxford University Press.

World Bank. 2000. *World Development Report: Attacking Poverty*. New York: Oxford University Press.

World Health Organization (WHO). 2000. *World Health Report*. Geneva: World Health Organization.

## Annex A: Assessment Methodology

### List of Indicator (Tracer) Items

Acetylsalicylic acid tablet 100 mg  
Amoxicillin capsule 500 mg  
Amoxicillin suspension 50 mg/ml  
Benzylpenicillin benzathine bottle/ampule 1,200,000 IU  
Captopril tablet 25 mg  
Cimetidine tablet 200 mg  
Diazepam tablet 10 mg  
Erythromycin oral 25 mg/ml  
Erythromycin tablet 500 mg  
Glibenclamide tablet 5 mg  
Hydrochlorothiazide tablet 50 mg  
Male condom  
Measles vaccine  
Mebendazole suspension 20 mg/ml  
Metronidazole tablet 250 mg  
Oral rehydration salts (envelope)  
Paracetamol solution 100 mg/ml  
Propranolol tablet 40 mg  
Salbutamol solution 2 mg/5 ml, ampule 120 ml  
Sulfamethoxazol + Trimethoprim tablet 400 + 80 mg

### Sample Selection

The population of the state of Minas Gerais in 2001 was estimated to be 17,689,658 inhabitants distributed throughout 12 administrative regions. The two selected mesoregions of Norte de Minas and Vale de Jequitinhonha cover approximately 12 percent (2,985,070) of the population in the state and were selected on the basis of their low socioeconomic development. There are seven microregions in the mesoregion of Norte de Minas and five in the mesoregion of

Jequitinhonha. Table 1 presents the estimated population and the scores for the Human Development Index (HDI) for 1991 (IBGE).

**Table 1. Population in 2001 and Human Development Index 1991 by Selected Municipality—Mesoregions of Jequitinhonha and Norte de Minas**

Mesoregion/Microregion	Population	HDI 1991
Jequitinhonha		
Diamantina	80,057	0.565
Capelinha	184,324	0.447
Araçuaí	145,707	0.426
Pedra Azul	86,385	0.458
Almenara	166,350	0.440
<b>Total</b>	<b>662,823</b>	<b>—</b>
Norte de Minas		
Janaúria	249,016	0.449
Janaúba	232,677	0.457
Salinas	178,886	0.424
Pirapora	151,400	0.557
Montes Claros	508,958	0.576
Grão Mogol	39,999	0.465
Bocaiúva	61,320	0.525
<b>Total</b>	<b>1,422,256</b>	<b>—</b>

The criteria for the selection of the municipalities that were included in the survey were—

- a) HDI score lower than that of the state as a whole for the year 1991, which was 0.699
- b) Main municipality in the microregion and/or meets criterion “c”
- c) Existence of clinic and outpatient facilities representing the various sectors studied (public, private, NGO/philanthropic) and private pharmacies (each municipality was to have at least two active facilities during the period of the survey)
- d) Geographic distribution of the sample not too dispersed (six days and 20 data collectors are available for the data collection)

On the basis of these criteria, 12 municipalities were selected from four microregions of Norte de Minas (Janaúba, Porteirinha, Salinas, Taiobeiras, Rio Pardo de Minas, Buritizeiro, Pirapora, Várzea da Palma, Brasília de Minas, Coração de Jesus, Francisco Sá, and Montes Claros), and seven were selected from two microregions of Jequitinhonha (Diamantina, Datas, Gouvêa,

Capelinha, Carbonita, Itamarandiba, and Minas Novas). Table 2 presents the estimated population for these areas for 2001 and their HDI scores for 1991.

**Table 2. Population in 2001 and HDI (1991) by Selected Municipality—Mesoregions of Jequitinhonha and Norte de Minas**

Mesoregion/Microregion/Municipality	Population	HDI 1991
<b>Jequitinhonha</b>		
Diamantina	<b>80,057</b>	<b>0.565</b>
Datas	5,629	0.528
Diamantina	42,781	0.616
Gouvêa	11,254	0.567
Capelinha	<b>184,324</b>	<b>0.447</b>
Capelinha	31,767	0.465
Carbonita	10,288	0.468
Itamarandiba	28,036	0.448
Minas Novas	28,518	0.405
<b>Norte de Minas</b>		
Janaúba	<b>232,677</b>	<b>0.457</b>
Janaúba	64,346	0.549
Porteirinha	33,203	0.422
Salinas	<b>178,886</b>	<b>0.424</b>
Rio Pardo de Minas	26,230	0.386
Salinas	34,064	0.452
Taiobeiras	21,055	0.476
Pirapora	<b>151,400</b>	<b>0.557</b>
Buritizeiro	22,200	<b>0.467</b>
Pirapora	51,179	0.678
Várzea da Palma	33,168	0.544
Montes Claros	<b>508,958</b>	<b>0.576</b>
Brasília de Minas	26,929	0.465
Coração de Jesus	27,406	0.469
Francisco Sá	22,190	0.471
Montes Claros	295,184	0.687

Once the municipalities were selected, the existence of facilities in the municipalities were confirmed. Information was obtained from various sources. The National Survey of Medical and Health Care (Pesquisa de Assistência Médico-Sanitária) (IBGE, 1999) and other data sets from the computerized SUS database (DATASUS, 2001) were also used to identify active facilities according to their legal nature (private, public, NGO, etc.) (Table 3). To identify private pharmacies and hospitals, including those not linked to the SUS system, the Register of Employers (*Cadastro de Estabelecimentos Empregadores*), published by the Ministry of Work

and Finance (Table 4), was consulted. As a follow-up, a telephone call was placed to confirm the information and to develop a final list of facilities that could be included in the survey sample and possible substitutes if needed. Table 5 presents the number of facilities that were surveyed by type of facility and municipality. Tables 6 through 13 present more detail about the sample, specifically about the availability of outpatient services and dispensaries.

**Table 3. Network of Outpatient Services Linked to SUS, by Municipality and Legal Affiliation**

Municipality	MOH, SHS, MHS	Foundation	Self-Management	Business	Philanthropic	Mixed Economy	Cooperative	Union	Beneficent	Total
Datas	6	0	0	0	0	0	0	0	1	7
Diamantina	19	0	0	1	2	0	0	1	0	23
Gouvêa	7	0	0	0	1	0	0	0	0	8
Capelinha	24	0	0	1	0	0	0	0	0	25
Carbonita	6	0	0	0	1	0	0	0	0	7
Itamarandiba	16	0	0	0	1	0	0	0	0	17
Minas Novas	7	1	0	0	0	0	0	0	0	8
Janaúba	9	0	0	8	1	0	0	0	0	18
Porteirinha	9	0	0	2	1	0	0	0	0	12
Rio Pardo de Minas	8	1	0	0	0	0	0	0	0	9
Salinas	10	0	0	1	1	0	0	0	0	12
Taiobeiras	4	1	0	0	0	0	0	0	0	5
Buritizero	10	1	0	0	0	0	0	0	0	11
Pirapora	10	0	0	1	0	1	2	2	0	16
Várzea da Palma	10	0	0	2	0	0	0	1	0	13
Brasília de Minas	9	0	0	0	1	0	0	0	0	10
Coração de Jesus	13	0	0	0	2	0	0	0	0	15
Francisco Sá	7	1	0	1	0	0	0	0	0	9
Montes Claros	29	2	3	22	3	0	1	0	0	60
<b>Total</b>	<b>213</b>	<b>7</b>	<b>3</b>	<b>39</b>	<b>14</b>	<b>1</b>	<b>3</b>	<b>4</b>	<b>1</b>	<b>285</b>

Source: IBGE/Pesquisa de Assistência Médico-Sanitária, Minas Gerais, 1999.

**Table 4. Health Facilities by Type of Activity, by Municipality**

<b>Municipality</b>	<b>Hospital Care</b>	<b>Other Professional Health Care</b>	<b>Pharmacy</b>	<b>Other Health Care Activities</b>
Capelinha	1	2	7	2
Carbonita	1	1	4	0
Itamarandiba	1	8	7	1
Minas Novas	1	0	7	2
Datas	1	0	1	0
Diamantina	2	20	13	15
Gouvêa	1	1	4	2
Janaúba	8	17	37	10
Porteirinha	3	2	8	4
Brasília de Minas	2	3	6	2
Coração de Jesus	2	1	9	2
Francisco Sá	1	0	6	4
Montes Claros	32	218	142	125
Buritizeiro	1	0	4	1
Pirapora	3	32	26	18
Várzea da Palma	2	6	7	4
Rio Pardo de Minas	1	0	8	1
Salinas	2	2	15	5
Taiobeiras	2	2	9	1
<b>Total</b>	<b>67</b>	<b>315</b>	<b>320</b>	<b>199</b>

Source: List of facilities, Ministry of Labor and Employment.

Table 5. Number of Services Sampled According to Type of Facility and Municipality

Municipality	Type of Facility										Total
	Public				Private			NGO/Phil.			
	Municipal Secretariat of Health Medical Stores	Hospital	Clinic	Pharmacy	Hospital	Clinic	Pharmacy	Hospital	Clinic		
Diamantina	1	0	2	1	0	2	1	2	0	9	
Datas	1	0	1	0	0	0	1	1	0	4	
Gouvêa	1	0	1	1	0	0	2	1	0	6	
Capelinha	1	0	1	1	0	1	1	1	0	6	
Carbonita	1	0	0	0	0	0	0	1	0	2	
Itamarandiba	1	0	1	0	0	0	1	1	0	4	
Minas Novas	1	0	0	0	0	0	0	1	0	2	
Janaúba	1	0	1	1	1	1	2	1	0	8	
Porteirinha	1	0	1	1	1	0	1	1	0	6	
Rio Pardo de Minas	1	0	1	1	0	0	1	1	0	5	
Salinas	1	1	1	1	1	1	2	1	1	10	
Taiobeiras	1	0	1	1	0	0	1	1	0	5	
Buritzeiro	1	1	1	0	0	0	1	0	0	4	
Pirapora	1	1	1	1	2	1	1	1	0	9	
Várzea da Palma	1	1	1	0	1	1	1	0	0	6	
Brasília de Minas	1	0	1	1	0	0	2	1	0	6	
Coração de Jesus	0	0	0	0	0	0	0	2	0	2	
Francisco Sá	1	0	1	1	1	0	1	0	0	5	
Montes Claros	1	1	0	0	2	3	1	2	0	10	
<b>Total</b>	<b>18</b>	<b>5</b>	<b>16</b>	<b>11</b>	<b>9</b>	<b>10</b>	<b>20</b>	<b>19</b>	<b>1</b>	<b>109</b>	

Note: NGO = nongovernmental organization, Phil. = philanthropic.

**Table 6. Philanthropic Hospital Outpatient Services with Dispensaries, by Municipality**

<b>Municipality</b>	<b>Philanthropic Hospitals</b>	<b>Outpatient Services with a Dispensary</b>
Brasília de Minas	1	1
Buritzeiro	0	0
Capelinha	1	0
Carbonita	1	0
Datas	1	0
Diamantina	2	0
Francisco Sá	0	0
Gouvêa	1	0
Itamarandiba	1	0
Janaúba	1	0
Minas Novas	1	0
Montes Claros	2	0
Pirapora	0	0
Porteirinha	0	0
Rio Pardo de Minas	1	0
Salinas	1	1
Taiobeiras	1	0
Várzea da Palma	0	0
<b>Total</b>	<b>15</b>	<b>2</b>

Source: Telephone survey by NESCON (May 2001).

Table 7. Private, for-Profit Outpatient Services with Dispensaries, by Municipality

Municipality	Private Hospitals	Outpatient Services with a Dispensary
Brasília de Minas	0	0
Buritzeiro	0	0
Capelinha	0	0
Carbonita	0	0
Datas	0	0
Diamantina	0	0
Francisco Sá	1	1
Gouvêa	0	0
Itamarandiba	0	0
Janaúba	1	0
Minas Novas	0	0
Montes Claros	1	0
Pirapora	2	0
Porteirinha	2	0
Rio Pardo de Minas	0	0
Salinas	2	1
Taiobeiras	0	0
Várzea da Palma	1	0
<b>Total</b>	<b>10</b>	<b>2</b>

Source: Telephone survey by NESCON (May 2001).

**Table 8. Public Hospitals with Outpatient Dispensaries, by Municipality**

<b>Municipality</b>	<b>Public Hospitals</b>	<b>Outpatient Services with a Dispensary</b>
Brasília de Minas	1	1
Buritzeiro	1	0
Capelinha	0	0
Carbonita	0	0
Datas	0	0
Diamantina	0	0
Francisco Sá	0	0
Gouvêa	0	0
Itamarandiba	1	0
Janaúba	0	0
Minas Novas	0	0
Montes Claros	0	0
Pirapora	1	1
Porteirinha	1	0
Rio Pardo de Minas	0	0
Salinas	1	1
Taiobeiras	0	0
Várzea da Palma	0	0
<b>Total</b>	<b>6</b>	<b>3</b>

Source: Telephone survey by NESCON (May 2001).

**Table 9. Philanthropic Outpatient Services (Clinics) with a Dispensary, by Municipality**

<b>Municipality</b>	<b>Philanthropic Outpatient Services with a Dispensary</b>
Brasília de Minas	0
Buritizeiro	0
Capelinha	0
Carbonita	0
Datas	0
Diamantina	0
Francisco Sá	0
Gouvêa	0
Itamarandiba	0
Janaúba	0
Minas Novas	0
Montes Claros	2
Pirapora	0
Porteirinha	0
Rio Pardo de Minas	0
Salinas	0
Taiobeiras	1
Várzea da Palma	0
<b>Total</b>	<b>3</b>

Source: Telephone survey by NESCON (May 2001).

**Table 10. Private, for-Profit Outpatient Services (Clinics) with Dispensaries, by Municipality**

Municipality	Private, for-Profit Outpatient Services with Dispensaries
Brasília de Minas	0
Buritzeiro	0
Capelinha	0
Carbonita	0
Datas	0
Diamantina	0
Francisco Sá	1
Gouvêa	0
Itamarandiba	0
Janaúba	0
Minas Novas	0
Montes Claros	1
Pirapora	0
Porteirinha	0
Rio Pardo de Minas	0
Salinas	5
Taiobeiras	0
Várzea da Palma	0
<b>Total</b>	<b>7</b>

Source: Telephone survey by NESCON (May 2001).

**Table 11. Public Outpatient Facilities (Health Centers) with a Dispensary by Municipality**

Municipality	Public Outpatient Facilities (Health Centers) with a Dispensary
Brasília de Minas	3
Itamarandiba	13
Rio Pardo de Minas	0
Datas	1
Diamantina	0
Gouvêa	1
Capelinha	0
Minas Novas	1
Carbonita	1
Salinas	0
Taiobeiras	0
Janaúba	9
Montes Claros	0
Porteirinha	0
Várzea da Palma	2
Pirapora	0
Francisco Sá	3
Buritizeiro	0
<b>Total</b>	<b>34</b>

Source: Telephone survey by NESCON (May 2001).

**Table 12. Other Outpatient Services with a Dispensary, by Municipality**

Municipality	Outpatient Services with a Dispensary
Brasília de Minas	0
Buritizeiro	0
Capelinha	0
Carbonita	0
Datas	0
Diamantina	0
Francisco Sá	0
Gouvêa	0
Itamarandiba	0
Janaúba	0
Minas Novas	0
Montes Claros	18
Pirapora	0
Porteirinha	0
Rio Pardo de Minas	0
Salinas	0
Taiobeiras	0
Várzea da Palma	0
<b>Total</b>	<b>18</b>

Source: Telephone survey by NESCON (May 2001).

Table 13. Municipal (Public) Pharmacies, by Municipality

Municipality	Municipal Pharmacies
Brasília de Minas	1
Buritzeiro	1
Capelinha	1
Carbonita	0
Datas	0
Diamantina	1
Francisco Sá	1
Gouvêa	1
Itamarandiba	1
Janaúba	1
Minas Novas	0
Montes Claros	0
Pirapora	1
Porteirinha	1
Rio Pardo de Minas	1
Salinas	1
Taiobeiras	1
Várzea da Palma	0
<b>Total</b>	<b>13</b>

Source: Telephone survey conducted by NESCON (May 2001).



### **National Minimum Compulsory List of Drugs**

Amoxicillin 500 mg capsule  
Amoxicillin powder 50 mg/ml suspension  
Benzylpenicillin benzathine 1,200,000 IU injection  
Benzylpenicillin procaine 400,000 IU injection  
Captopril 25 mg tablet  
Carbamazepine 200 mg tablet  
Digoxin 0.25 mg tablet  
Erythromycin 500 mg tablet  
Erythromycin 25 mg/ml suspension  
Phenobarbital 100 mg tablet  
Phenobarbital oral solution, 40 ml bottle  
Glibenclamide 5 mg tablet  
Hydrochlorothiazide 50 mg tablet  
Mebendazole 100 mg tablet  
Mebendazole oral suspension 100 mg/5 ml  
Metronidazole 250 mg tablet  
Metronidazole oral suspension 20 ml/5 ml  
Nystatin vaginal cream 250,000 IU/tablet  
Paracetamol 500 mg tablet  
Propranolol 40 mg tablet  
Oral rehydration salts 27.9 g powder/envelope  
Salbutamol 2 mg tablet  
Salbutamol 2 mg syrup  
Sulfamethoxazol + Trimethoprim 400 + 80 mg tablet  
Sulfamethoxazol + Trimethoprim 200 mg + 40 mg/5 ml suspension  
Ferrous sulfate 40 mg Fe tablet  
Ferrous sulfate 25 mg Fe/ml oral solution 30 ml

## Essential Drugs List, Minas Gerais

Acetylsalicylic acid 100 mg tablet  
Acetylsalicylic acid 500 mg tablet  
Folic acid 5 mg tablet  
Aminophylline 100 mg tablet  
Amitriptyline 25 mg tablet  
Amoxicillin 500 mg capsule  
Amoxicillin powder 50 mg/ml suspension  
Benzylpenicillin benzathine 1,200,000 IU injection  
Benzylpenicillin procaine + potassium 400,000 IU injection  
Captopril 25 mg tablet  
Carbamazepine 200 mg tablet  
Cimetidine 200 mg tablet  
Dexamethasone cream 0.1% tube  
Dexchlorpheniramine oral solution 0.4 (maleate) mg/ml  
Diazepam 10 mg tablet  
Digoxin 0.25 mg tablet  
Dipyrrone 500 mg/ml oral solution  
Erythromycin 250 mg tablet  
Erythromycin 25 mg/ml suspension  
Phenytoin 100 mg tablet  
Phenobarbital 100 mg tablet  
Furosemide 40 mg tablet  
Glibenclamide 5 mg tablet  
Haloperidol 1 mg tablet  
Haloperidol 5 mg tablet  
Hydrochlorothiazide 50 mg tablet  
Imipramine 25 mg tablet  
Mebendazole 100 mg tablet  
Mebendazole 4% suspension  
Metronidazole 250 mg tablet  
Metronidazole 4% suspension  
Methyldopa 500 mg tablet  
Neomicyn + Bacitracin 5 mg + 250 IU/g tube  
Nifedipine 20 mg tablet  
Nystatin vaginal cream 5,000 IU/g tube

Paracetamol 500 mg tablet  
Propranolol 40 mg tablet  
Oral rehydration salts powder/envelope  
Salbutamol 0.4 mg/ml oral solution  
Sulfamethoxazol + Trimethoprim 400 + 80 mg tablet  
Sulfamethoxazol + Trimethoprim 4% + 0.8 suspension  
Ferrous sulfate 25 mg Fe/l oral solution

## Over-the-Counter Medicines

Analgesics (not narcotics) for simple headache and pain

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Anthelmintics, gastrointestinal use only  
Antihemorrhoidals  
Anti-infectives for application in the throat (mostly solutions that do not include antibiotics or sulfa drugs)  
Balsams and mucolytics for inhalation  
Dietetic supplements with vitamins  
Enzymatic digestives  
Eyedrops for emollient, protective, or anesthetic use  
Gynecologic antiseptics, spermicides (except hormones and antibiotics), vaginal use contraceptives  
Immunizing vaccines  
Intestinal absorbents  
Iron preparations, simple liver extracts  
Liver protection preparations  
Nasal isotonic solutions containing mostly sodium chloride  
Natural and homeopathic products  
Oral hydration electrolytes  
Paste for prophylaxis of dental caries  
Simple antacids with antiseptics or carminatives  
Simple urinary antiseptics  
Skin preparations (keratolytics, emollients, astringents, rubefacients, antiseptics, and disinfectants)  
Smooth laxatives  
Tonics  
Topical anti-inflammatories, antirheumatics  
Vitamin B complex with up to three B vitamins, and polyvitamins with minerals



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## Annex D: List of Key Persons Interviewed

Carlos Alberto Gomes (Secretaria de Políticas de Saúde, Gerência Técnica de Assistência Farmacêutica, Ministério da Saúde)

Miriam Araújo Coelho Tibúrcio (President COSEMS—Mina Gerais)

Dr. Júlio César (Director, Vigilância Sanitária, SES—Mina Gerais)

Dr. Jorge Bermudez (School of Public Health, FIOCRUZ)

Rilke Novato Públio (Diretor, Conselho Regional da Farmácia de Minas Gerais)

Angela Ferreira Vieira (Secretária Geral de Farmácia, Conselho Regional da Farmácia de Mina Gerais)

Virgílio Baião Carneiro (President of Associação dos Serviços Assistenciais de Saúde Próprios de Empresas, Minas Gerais)

Geraldo Adão Santos (Conselho Municipal de Saúde, Nova Lima, Mina Gerais—CNS)

Guilherme Emrich (Biobrás, S.A.)

Ciro Mortella (ABIFARMA)

Sid Manso (Universidade Estadual do Rio de Janeiro)

Gabriela Bittencourt Gonzalez Mosegui (Universidade Estadual do Rio de Janeiro)

Dr. Basílio (Professor, Internato Rural de Farmácia, Universidade Federal do Minas Gerais)

Tarcisio de Campos Ribeiro (General Superintendent, FUNED)

Maria Regina de Araújo Borges (Production Director, FUNED)

Kleyde de Carvalho Teixeira (Coordinator Department of Quality Control, FUNED)

Tânia Mara (Vigilância Sanitária, Minas Gerais)

Dr. Mauro Chrysóstomo Ferreira (Director UNIMED Belo Horizonte)

Dr. Ruy Marroig (GRUPO RENASCER)

Jane Daise (Farmacêutica, Diamantina, Minas Gerais)

Lazaroo Luiz Gonzaga (Presidente do Sindicato do Comércio Varejista de Productos Farmacêuticos do Estado de Minas Gerais)

José Alves Torres (Sindicato do Comércio Varejista de Productos Farmacêuticos do Estado de Minas Gerais)

Marcos Crus de Souza (Sindicato do Comércio Varejista de Productos Farmacêuticos do Estado de Minas Gerais)

José Wanderley Volada (Sindicato do Comércio Varejista de Productos Farmacêuticos do Estado de Minas Gerais)

Federico Quintão (Sindicato do Comércio Varejista de Productos Farmacêuticos do Estado de Minas Gerais)