Country Profile

A look at the Pharmaceutical Industry in

BRAZIL

Produced in collaboration with ISPE Brazil

ISPE

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Dear ISPE Member,

Having a population of approximately 180 million inhabitants, Brazil is a country of large territorial extensions with different regional characteristics and huge coastlines that offer tourism during the whole year. Brazil also has economic centers with many of the world's major corporations.

Brazil has shown a stable economic panorama in the last 10 years with a controlled inflation level which has led to some big investments in the industrial sector.

In spite of the world's recession, Brazil has been appearing in the news reknowned for its representation in Latin America as well as countries in development.

The Brazilian pharmaceutical industry in particular has shown a good profit level and growth over the last several years.

Forecasters are predicting a 3% increase in the Gross Domestic Product (GDP) and the industries and trade are preparing for this increase in consumer demand.

The national pharmaceutical companies have found a strong and important partnership within the international capital, which is very important to the multinational companies that wish to manufacture and distribute their products in this market worth almost $ 6.5 billion. The local and international partnerships have offered to both sides a great opportunity for the country's development, expertise, and market growth.

In Latin America, Brazil has modern and well prepared industries able to meet the international demands, producing locally and meeting the needs of the whole continent.

Brazil is a country whose population is famous for its hospitality and is happy to invite you to visit. We hope you get delighted to see all the wonderful things that a tropical country can offer you.

Silas Teles Filho

Silas Teles Filho
President, ISPE Brazil Affiliate
2000 - 2004

This feature in *Pharmaceutical Engineering* is designed so that you can tear it out, three hole drill (if desired), and keep it with other Country Profiles as they are published.

Look for the Country Profile on Canada in the March/April issue of *Pharmaceutical Engineering.*

A View of the Brazilian Pharmaceutical Industry

by Antônio Costa, ex. Altana Pharma Market Research and GRUPEMEF (Pharmaceutical Market Researcher Group)

Brazil is a country of large territorial extension (8,547,403 km^2) full of cultural and economic diversities that cause a huge contrast in regional and economic habits. It has a pharmaceutical industry complex with 239 companies. Out of those, 178 are Brazilian and most of the big companies are situated in the south and southeast zones, mainly in two states, São Paulo and Rio de Janeiro.

The industrial development is linked to the state and metropolitan government actions that have increased fiscal incentives in order to get the installation of new plants.

The estimated billing for 2004 is of $5.5 billion to sales of 1.3 billion units. From this billing, 36% come from Brazilian companies, 23% from American companies, 16% from German companies, and 11% from Swiss companies - *Table A and Figures 1-3*.

From the total of the pharmaceutical market, approximately 21% of the billing comes from the Over the Counter (OTC) section.[1]

Generic drugs as well as products containing phytotherapeutic agents have grown considerably in the last five years. The generic products growth is due to governmental policy of costs reduction which currently represents 7.3%. The phytotherapeutic agents have gained market share due to favorable factors such as growing acceptance of doctors and patients and profitability, resulting in higher investments by the industries in this sector.

The phytotherapeutic products, historically dominated by German companies, are currently receiving a lot of investments within the national companies such as Laboratories Aché (the largest Brazilian Company) as well as other companies that work exclusively in this area such as Herbarium and Flora Medicinal (now Natura cosmetics). This sector should grow an average of 10% a year.

This sector has received academic as well as local industrial attention due to the large diversity in Brazilian flora, mainly in the north and northeast regions, where there are many different medicinal plants.

Companies	Share (%)
Laboratórios Aché *	6.28
Aventis Pharma	5.76
EMS Sigma Pharma *	5.47
Novartis	4.72
Roche	4.48
Boehringer Ing	4.32
Schering do Brasil (AG)	3.88
Schering Plough	3.53
Medley *	3.44
Pfizer	3.25
* Brazilian Companies	

Table A. Ten main laboratories in billing.

As one of the most important centers of exportation in Latin America, Brazil shows a growth expectation of 10% in relation to last year; a period which has ex-

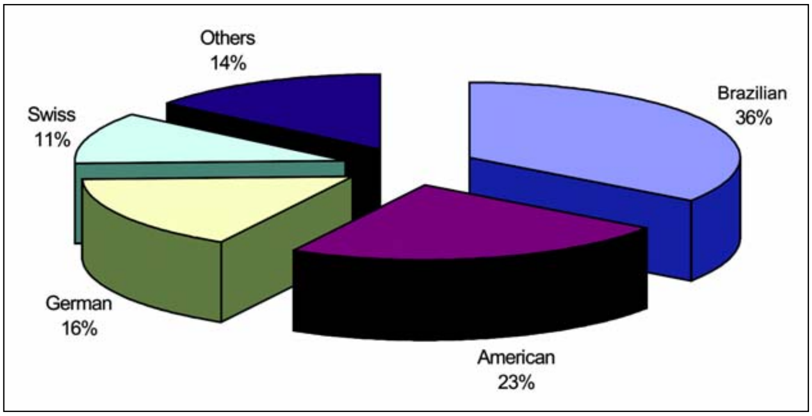

Figure 1. Market share (USD) by country.[3]

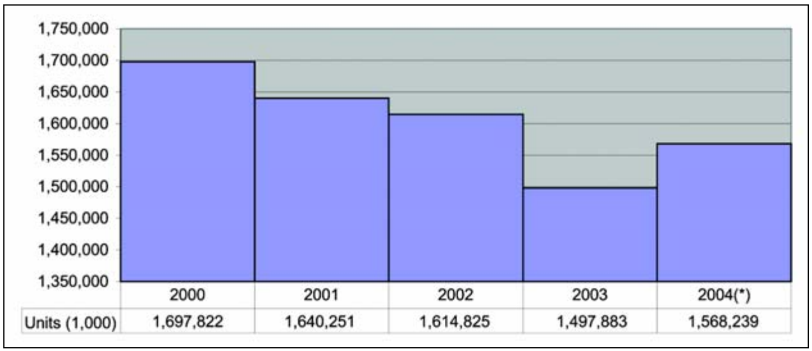

Figure 2. Brazilian pharmaceutical market in units (1,000).[1]

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Research and Development

by Carlos A. Morales Paris, MD, Apsen Pharmaceutical Medical and R&D Director

Since the mid '90s, the Brazilian pharmaceutical industry has invested $2 billion in the building, modernization, expansion of production lines resulting in the introduction of top products and an increase of scale and productivity (FEBRAFARMA).

Due to the high competition and the tough rivalry among the manufacturers in the country, approximately 2,000 new drugs have been launched in the last seven years.

A relevant event was the introduction of generic named drugs to the Brazilian market in 1999. It generated the availability of 4,500 equivalent drugs. It not only increased the variety of drugs in the market, but also gave the consumer the option of having cheaper products with the same quality of the known brands.

This initiative received investments of R$ 1 billion reais in building and modernizing the plants. It directly created 10 thousand new jobs and resulted in the opening of 20 new laboratories specialized in bioequivalence tests

The pharmaceutical industry invests the equivalent of 21% of the sales in Research and Development, four times more than in the sectors traditionally associated with modern technologies, such as automobiles, electronics and telecommunications.

This demonstration of technological, managerial, and market capacity is still more important since the pharmaceutical industry in the country is doing well in an adverse economic environment which there is a taxation level of 23% (one of the highest in the world). In Portugal, for instance, the tax on medicine is 4.7%) and a price control policy that suffocates the companies and inhibits the sector's development.

Each year, more and more national and international laboratories try hard to discover and synthesize new active substances, taking advantage, among other factors, of the Brazilian biodiversity.

The Center of Biotechnology of Amazonia (CBA) invested R$14 million to build a complex of 12,000 square meters, which is situated in the area of the industrial state of Manaus, and will have the units of basic and advanced research of cosmetic companies, phytotherapeutic agents, and extracts that

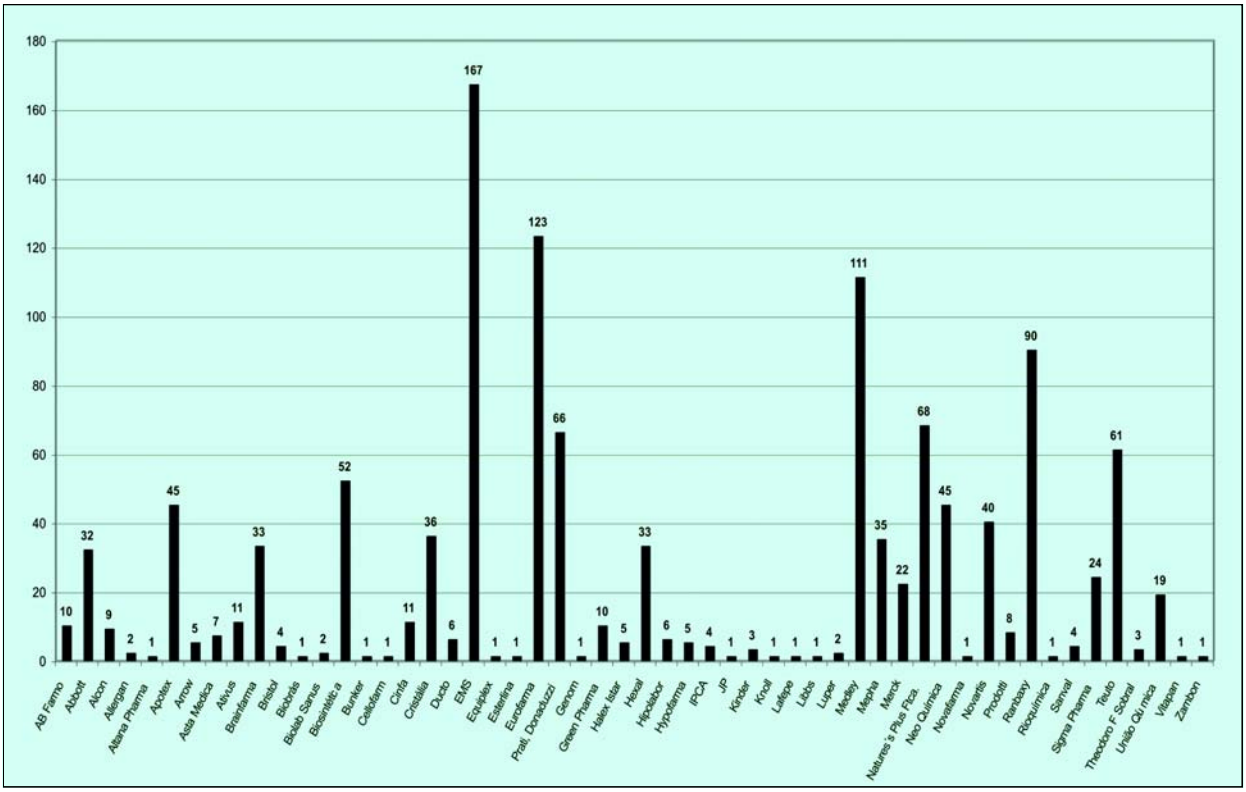

Figure 1. Total of registered generic drugs by company.

use the raw material from the Amazonica region, the planet's highest concentration of biodiversity. CBA was built using mainly the resources of the Zona Franca de Manaus Superintendency [Suframa that today is under the Ministry of Development, Industry, and Foreign Trade (MDIC) and Science and Technology (MCT) and Environment (MMA).]

According to the CBA technical assessor, Imar Cézar de Araújo, by the end of 2004, the first 11 laboratories (from the total of 26) will be operational. Araújo explains that the programs to be developed represent in the medium and long run, the possibility of multiple opportunities of investments necessary to the installation of a bioindustry park which will attract new companies, enterprises, and businesses. To enable this, according to the coordinator, it is necessary to have qualified workers, opening new opportunities to researchers of the region and of the country.

The center also will stimulate the areas of science, technology, and technological innovation to increase competition of the so-called bioproducts, and of the farming products produced in the Amazonas region. Among the activities, there are the certification of the natural products from Amazonas, having a quality assurance stamp (CBA stamp) and the transfer of the technology of processes and patents developed at the center and at the Rede de Laboratórios Associados - Net Associated Laboratories (RLA). The net will link universities and public and private research centers, such as Instituto Nacional de Pesquisas da Amazônia, Museu Emílio Goeldi and Federal Universities of Amazonas and Pará and also Fundação Fiocruz and Oswaldo Cruz among others.

The CBA was created in the scope of Brazilian Program of Molecular Ecology for the Supported Use of Amazonas Biodiversity (Probme/Amazônia), and this year, it has been included in the government industrial, technological, and international trade policy. According to the technical assessor, the center will have a laboratory complex of international standard aiming the applied research, technology transfers, and rendering services of a high level. When those projects are implemented, CBA will act in bioprospection identifying and extracting the active ingredients from plants and animals to pharmaceutical use, as for example, antibiotics, anti-neoplastics, anti-hypertensive substances, and different products as vegetal raw material to make biocosmetics, natural colorants, aromatic substances, essential oil, biodegradable polymers, bio-insecticides among others. In the section of phytotherapeutic, phyto-cosmetics, and fruit culture, CBA was projected to also attract new business and new companies strengthening the productive chain with the consequent settlement of small producers.

A View of the Brazilian Pharmaceutical Industry

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ported the equivalent of $279.9 million. In the first six months of 2004, Brazilian pharmaceutical companies have exported $163.9 million in finished medicine and similar products, vaccine, serum, blood derived products, and parenteral solutions, a growth of 17.85% in relation to the same period last year. The exportations to Mercosur increased 14.77% in the first quarter comparing to the same period last year, and the result was $43.6 million. The most important import markets last year were Mercosur; Argentina, Mexico, and Venezuela.[2]

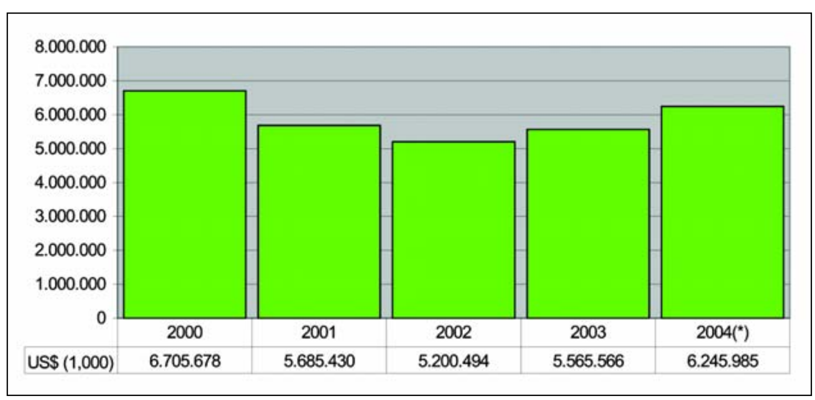
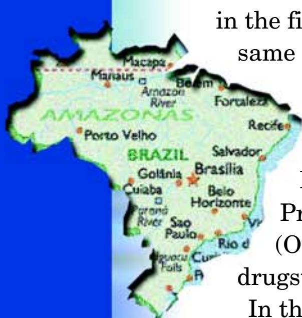


Figure 3. Brazilian pharmaceutical market in USD$ (1,000).[1]



Prescription drugs as well as Over the Counter (OTC) products are primarily distributed through drugstores/pharmacies, clinics and hospitals.

In the retail, there are 55,000 points of sale (drugstores/pharmacies) in Brazil, with an average of 23% of the products that are not medicine (cosmetics, hygiene, etc.) and 77% of medicine.[2]

The demand of the products is mainly originated by the doctors' prescriptions, in which the industries invest 80% to 85% of the marketing amount. Using the

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Brazilian Pharmaceutical Market

by Antônio Costa, ex. Altana Pharma Market Research and GRUPEMEF (Pharmaceutical Market Researcher Group) and Sérgio Mena Barreto, ABRAFARMA President

In Brazil, there are some class associations that represent the pharmacies such as the Brazilian Association of Pharmacies (ABRAFARMA), the Brazilian Association of Pharmaceutical Trade (ABCFARMA), among others. Both associations represent a total of 90% of the retail pharmaceutical market.

ABRAFARMA was founded to be representative and to be trusted by the government in negotiations of the sector.

ABRAFARMA is the reunion of 28 companies with the biggest drugstores in Brazil having 1,800 stores. The association represents around 27% of the medicine in Brazilian market and involves R$5.6 billion per year. 25% of the sales are of non-medicine products. Founded in 1991, it has companies in 237 cities in 19 Brazilian states that employ 33,284 people. It focuses on the improvement of the associated companies to preserve the institutional image, the relationship with public institutions, government and suppliers, and also the legal support and market research to improve the activities.

In Brazil today, the drugstores survive due to the sales of products that aren't medicine. In a traditional drugstore, 75% of the sales are of drugs, 25% are shampoos, diapers, hair color, blood glucose monitoring systems, vitamins among others. The small stores have low billing and high informal level with a monthly income between R$ 30,000 and R$ 40,000. (Source: ABRAFARMA)

The research also has shown an increase of 12.21% in the number of product units sold and the delivery system already represents 3.61% of the sales.

In Brazil, there are 53,000 drugstores, 80% of them are small stores with low billing and high informally level with monthly income between R$30,000 and R$ 40,000.

The initial investment to open a drugstore is low. It is possible to buy a drugstore for R$ 50,000,00 or R$ 70,000,00. Drugstores in Brazil earn their profit primarily through the sale of non-medicine products. Abrafarma final net profit is around 1.5%. The data have been audited by Fundação Instituto de Administração (Fia). This result is generated by the non-medicine products. The organization completely supports the initiative of the President Luiz Inácio Lula da Silva in reducing the State VAT (ICMS) of the medicines in Brazil. If he manages to do that, the Federal Government will solve the problem of inequity that has been happening with millions of Brazilians: the huge amount of taxes that the patient has to pay on drugs.

In Brazil, the State VAT on medicine is between 17% and 19%. Those high taxes increase the price of the drugs to the final consumer; burden the companies that pay more. ABRAFARMA has been trying to negotiate with the government a tax reduction to 7%. Today, the level of taxes is 18%.

The solution to provide medicine for a country with 180 million people is to offer individuals the generic drugs; the government provides medicine to the population that can afford a treatment that is 40% cheaper. And the popular drugstore was started to help those people whose income is between two and three minimum wages and can afford very little. But there is a big part of the population that the solution is the distribution of free medicine performed by Sistema Único de Saúde = Unique Health System (SUS) maintained by the government.

At the popular drugstore, people can find 86 drugs at low prices. Doctors prescribe 10 thousand drugs in Brazil. At the popular drugstore, 70% of the products are of public production. So, out of the 86 drugs prescribed, 77 are of public production and the other 19, bought from private industries. They are products of good quality.

The number of jobs in drugstores is increasing because it is easy to open a drugstore, as long as you have an appropriate location and abide by government regulations. The City Hall requests a permission to work, controls, and registers a pharmacist. There are no obstacles. A medium-size drugstore can employ an average of 14 people in each store.

This is a situation that will change in a few years with the number of new colleges that have been opened lately; we should get to the year 2005 with a considerable number of graduated professionals. In Brazil, 14 thousand pharmacists graduate every year.

In charge of Abrafarma for the third time, Sérgio Mena Barreto fights for the regulation of many drugstores spread all over Brazil. He defends the reduction of the tax rate on medicine as well as government actions to allow the population access to medicine as in the use of generic drugs and the popular drugstore.

Professional Profile

by Renato Pimazzoni, President, Formil Pharmaceutical

The level of education required in the pharmaceutical industry is high because individuals are responsible for industrial, administrative, and commercial areas.

The professional working in the industrial arena must be graduated in chemist-pharmacy, industrial chemistry, engineering, and must have vast experience in the pharmaceutical sector.

The industrial area demands highly trained professionals in the production, products development, and quality control sectors.

Research and development in the Brazilian pharmaceutical industry is performed by a few companies that invest in new drugs research; one of the projects that has received attention from the government and from the largest Brazilian pharmaceutical laboratory (Laboratórios Aché) that includes phytoterapeutic agents due to the diversity of Brazilian flora.

Another professional of great importance is the one responsible for regulatory issues whose task is to register the products at the government Agência Nacional de Vigilância Sanitária (ANVISA).

The marketing of Brazilian pharmaceuticals is regulated by ANVISA and prohibits direct to consumer advertising. All technical information is exclusive to the doctor; therefore, the medical advertisement is the most important tool to advertise the product.

The Brazilian market has 140,000 doctors, of which 40% are in south and southeast regions which correspond to 60% of the prescriptions.

In a highly competitive market, the necessity to narrow the relationships with doctors and drugstores are the companies' basic strategies.

Thus, the company's marketing must be synchronized with the market and with its sales force, whereas the latter is the means of communication with the clients and also the information source about market acceptance and the competitors' actions.

The pharmaceutical industries professional representatives are highly trained, receiving instructions about pathologies and therapy as well as continuously updated market information. Today, 80% of the sales force has university degrees.

In addition to the distribution of medical advertisement, the professional representative visits the drugstores in order to obtain information about the company's product line, it's not a sales visit because the sales are performed by the suppliers/wholesalers.

To increase the visits to the doctors in some specialties, some companies hire a group of trainees (directly or through companies specialized in training and forming groups of representatives).

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media for OTC products, the investment is still too low, because most of the population still follows the advice of the drugstore professional.

The Brazilian pharmaceutical market shows a growth potential, mainly in drugs of continuous use, because the population of elderly is increasing while the birthrate is going down.

In Brazil, there is no medicine reimbursement system, therefore, the acquisition of a product is totally paid by the user, or it may be received free of charge through a governmental health organ, in the latter the patients must be enrolled in the organ.

The official government laboratories still don't have high productive capability and they produce some products for their own use in their hospitals, and these products cannot meet the necessity so the products are not sold in the selling points.

In the last five years, the national companies have intensified the partnerships with multinational companies, producing and selling their products, having as a result the investment in the modernization and automation of the industrial plants, and in many of them, including the ones belonging to the big international corporations.

The Brazilian pharmaceutical industries have today a modern industrial estate that meets all the international demands in quality control, and production capacity to internal and external market.

Sources

1. GRUPEMEF/FEBRAFARMA.
2. FEBRAFARMA.
3. IMS-MAT:Dec/03.

Brazilian Associations and Agencies

Brazilian Regulatory Agency

Agência Nacional de Vigilância Sanatária (ANVISA)

End.: SEPN 515, Bl B - Edifício Ômega
Brasilia - DF
Cep: 70.770-502
Brazil
www.anvisa.org.br

Brazilian Pharmaceutical Associations

Federação Brasileira da Indústria Farmacêutica (FEBRAFARMA)

Rua Alvorada, 1280 - Vila Olímpia
São Paulo / SP
Cep: 04550-004
Brazil
Tel: 55-11-3046-9292
www.febrafarma.org.br

Associação Brasileira da Indústria de Medicamentos Isentos de Prescrição (ABIMIP)

(OTC´s Brazilian Industry Association)
Rua Alvorada, 1280 - Vila Olímpia
São Paulo / SP
Cep: 04550-004
Brazil
Tel: 55-11-3045-3842
www.abimip.org.br

Associção dos Laboratórios Farmacêuticos Nacionais (ALANAC)

Rua Sansão Alves dos Santos, 433 - 8º. andar - Brooklin Paulista
São Paulo / SP
Cep: 04571-090
Brazil
Tel: 55-11-5506-8522
www.alanac.org.br

Associação de Indústria Farmacêutica de Pesquisa (INTERFARMA)

Rua Fernandes Moreira, 1166 - cjto. 72 - Santo Amaro
São Paulo / SP
Cep: 04716-003
Brazil
Tel: 55-11-5180-2380
Fax: 55-11-5183-4247
www.interfarma.org.br

Associação Brasileira de Medicamentos Genéricos (PRÓ-GENÉRICOS)

Rua Alvorada, 1280 - Vila Olímpia
São Paulo / SP
Cep: 04550-004
Brazil
Tel: 55-11-3897-9767
Fax: 55-11-3845-0742
www.progenericos.org.br

Associação Brasileira de Redes de Farmácias e Drogarias (ABRAFARMA)

Brazilian Pharmacy Association
www.abrafarma.com.br

Brazilian Entities

Associação Brasileira das Indústrias de Química Fina, Biotecnologia e suas Especialidades (ABIFINA)

http://www.abifina.org.br

Associação Brasileira da Indústria Farmoquímica (ABIQUIF)

http://www.abiquif.org.br

Associação Nacional de Farmacêuticos Magistrais (Anfarmag)

http://www.anfarmag.com.br

Grupo dos Profissionais Executivos do Mercado Farmacêutico (GRUPEMEF)

http://www.grupemef.com.br

Sociedade Brasileira de Vigilância de Medicamentos (Sobravime)

http://www.sobravime.org.br