

The Role of Governmental Policies in Nurturing the Pharmaceutical Industry in Brazil: The Mix of Centralized Procurement, Public Drug Production and Public-private Partnerships

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Abstract

The World Health Organization estimates that only approximately one third of the world population have regular access to essential medication. Most of the deprived households are in developing countries. Studies on the pharmaceutical industry are thus particularly relevant for improving the health situation of the developing world and to increase new drug development for diseases that afflict the poor. Furthermore, as a knowledge-intensive sector, the pharmaceutical industry is of strategic importance for decreasing the developing countries' dependence on foreign technology and to stimulate innovation. This paper is based on fieldwork visits to state-owned pharmaceutical laboratories and semi-structured interviews with key public officials in Brazil and aims to analyze what kind of policy mixture is the most effective in order to ensure access to essential medicines in developing countries and to nurture the growth of the domestic pharmaceutical industry. It shows that centralized public procurement is being used by the Brazilian government to nurture the development of the pharmaceutical industry and improve health care delivery. In addition, it demonstrates that the technology backwardness of the Brazilian pharmaceutical sector and the lack of alignment between the Ministry of Health's priorities and public laboratories' production activities are critical constraints for the sustainability of public health programmes in Brazil.

Keywords: Access to Essential Medicines; Centralized Procurement; Public Laboratories; Brazilian Pharmaceutical Industry.

Introduction

The purpose of this study is to analyze what kind of policy mixture is the most effective in order to ensure access to essential medicines in developing countries and to nurture the growth of the domestic pharmaceutical industry. It focuses upon the Brazilian case, in which centralized public procurement is being used to promote the development of domestic firms and foster innovation. In addition, some of the main constraints faced by the Brazilian government in implementing this

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approach will be presented in order to discuss how public health care delivery can be improved in the country.

There are a number of reasons why the pharmaceutical industry should be carefully considered by policy makers, especially in developing countries, and further studied by the academic community. The first reason is the need for developing countries to strengthen their domestic pharmaceutical industry in order to address the major health needs of their populations. The pharmaceutical industry is strategic for security reasons as it is intrinsically connected to health policies and to the population's well-being (Pradhan, 2006). The World Health Organization estimates that, in 1999, only approximately one third of the world population had regular access to essential medication. Most of the afflicted households reside in the developing world (WHO, 2004b: 61).

A second reason is the existence of the so-called neglected diseases, which demands a greater role of the pharmaceutical industry in developing countries. R & D investment of private firms for these types of diseases is insufficient, mainly due to the high costs of new drug development and the low profit potential, as neglected diseases usually afflict the poorest segments of the population (Hubbard and Love, 2005: 148; Chaudhuri, 2005: 8). According to MSF (2001: 11), "of the 1,393 total new drugs approved between 1975 and 1999, only 1% (13 drugs) were specifically indicated for a tropical disease". In this context, studies on the pharmaceutical industry are relevant to back up governmental policies aimed at facilitating the access to essential medicines for the poor and stimulating innovation in areas related to the epidemiological profile of the local population.

A third and most relevant reason is that governmental inability to stimulate local productivity may lead to significant trade deficit and to insufficient drug supply, resulting in vulnerability to epidemic outbursts. In Brazil, the impact of imported high-value added drugs on the Ministry of Health's budget is significant, which demonstrates a high level of dependence on foreign firms for the continuity of public health programmes. Pharmaceutical transnational firms have had a strong presence in drug manufacturing in the country, especially since the Second World War. At that time, technological constraints and the lack of new product manufacturing capacity resulted in an increasing number of joint ventures and mergers and acquisitions between domestic firms and transnational companies from the mid-1940s. As a result, the share of foreign control on the Brazilian pharmaceutical industry rose from 13.5% in 1930 to 45% in 1950 and 70% in 1960 (Bermudez, 1992: 21; Cytrynowicz, 2007: 100-101, 123-126). An annual ranking on the largest companies in Brazil published by the Brazilian magazine *Exame* shows that, in 2009, the top firms in the pharmaceutical industry were transnationals and they reported revenue considerably larger than that of domestic ones (*Exame*, 2009). In other developing countries such as India, which have a stronger domestic pharmaceutical sector than Brazil, the media has recently reported that transnational firms have taken over some of the main Indian pharmaceutical firms,¹ which is evidence of the increasing interest of transnational companies in the markets of emerging economies.

This paper is based on fieldwork visits and semi-structured interviews with key managers from two public laboratories in Brazil: Farmanguinhos (Institute for Technology in Pharmaceuticals) and Iquego (Chemical Industry of the State of Goiás). Additional interviews were also conducted with public officials from the Ministry of Health and from the Ministry of Development, Industry and Foreign Trade.

This article is divided into three sections. The next section describes the methodology used in this study. Section two presents the main advantages of centralized public procurement compared with decentralized one and how the Ministry of Health in Brazil is using its purchasing power to nurture the growth of the domestic pharmaceutical industry. The third section examines some of the main bottlenecks regarding centralized procurement and public drug production in the country. The main lessons drawn from this study are summarized in the conclusion.

1. Methodology

The lessons drawn from this present study are based on semi-structured interviews and fieldwork visits conducted from March to June 2010 in two public laboratories: Iquego, founded in 1964 in the city of Goiânia, and Farmanguinhos, founded in 1956 in Rio de Janeiro. In Brazil, public laboratories are state-owned facilities engaged in drug manufacturing. As of today, their production activities have been restricted to formulations and, therefore, they do not produce active pharmaceutical ingredients (hereinafter “APIs”). A few of these laboratories also undertake R & D activities and Farmanguinhos is the most prominent in this aspect, having 15 lines of research which include neglected diseases and HIV/AIDS. There are currently over 17 public facilities in Brazil, some of which are linked to local states, others to federal universities and others to the armed forces. Farmanguinhos is the only public laboratory which is directly linked to the Brazilian Federal Government (Ministry of Health).

Iquego and Farmanguinhos were selected for study because they are located in areas which have well-developed private pharmaceutical industrial clusters. This would help the analysis of the sustainability of public laboratories in regions where the private sector has a strong presence. Moreover, both Iquego and Farmanguinhos have significant production capacity and a long history of drug production, although their levels of development are uneven. While Farmanguinhos is well-known for its R & D activities, for several partnerships with private firms and universities and for being actively involved in public health policy discussions, Iquego has a more incipient R & D division and has shown a limited capacity to establish partnership with other organizations. However, Iquego, along with Farmanguinhos, is a major drug supplier for the Ministry of Health, and has a significant production of antiretroviral drugs (hereinafter “ARVs”) for the Brazilian HIV/AIDS programme. In addition, while Farmanguinhos is directly linked to the Ministry of Health, Iquego is controlled by the

local state of Goiás. The case study, therefore, provides evidence of the importance of centralized drug procurement also for public laboratories controlled by state level governments.

Farmanguinhos has a total of 1,032 employees, of which 111 are researchers — including 27 M. A. and 30 Ph. D. holders. This public laboratory has two facilities, one of approximately 6,000 m² of constructed area located in Manguinhos (Rio de Janeiro) and another one purchased from GlaxoSmithKline in 2005, with financial resources from the Ministry of Health, which has over 40,000 m² of constructed area and is sited in Jacarepaguá (Rio de Janeiro). The number of employees working at Iquego is considerably lower, 510 people, and its factory has a total constructed area of approximately 14,000 m².

For the case study, a thorough visit to the factory of Iquego was made, including in-depth interviews with the production manager, R & D manager, sales manager, quality control manager, logistics manager and strategic planning adviser. Farmanguinhos' new plant was also visited and a meeting was held with the laboratory's director, R & D manager, quality control manager and international relations adviser. The questions asked during the interviews tried to reach a deeper understanding of the production process of these public laboratories, including supply chain management, in order to analyze their contribution for the improvement of the Brazilian public health programmes. The managers were also inquired about the relationship between public laboratories and the Ministry of Health to observe to what extent these facilities have to follow the government priorities and to examine their level of interdependence to national public health policies. Furthermore, the interviews tried to identify the main constraints faced by these laboratories and what are their main strengths, i.e., how these public facilities can facilitate the growth of the Brazilian pharmaceutical industry and improve health care delivery in SUS (Unified Health System),² the Brazilian public health system.

In addition, four key public officials from the Ministry of Health and one from the Ministry of Development, Industry and Foreign Trade were interviewed from February to June 2010 to reach a deeper understanding of public policies for the health sector and to analyze what are the main initiatives to stimulate R & D activities and to promote innovation in the pharmaceutical and biotechnological sectors. In particular, the interviews at the Ministry of Health were important for analyzing the role of public laboratories in the current governmental health policy and for gathering more information on the newly designed public-private partnerships (hereinafter "PPPs") in the health sector. Three of these public officials were directly involved with drug procurement and one of them was a specialist on ARVs, under the HIV/AIDS programme. The interview at the Ministry of Development, Industry and Foreign Trade, on the other hand, was conducted in the Secretariat for Innovation, and was focused on obtaining information on governmental initiatives for promoting innovation in the pharmaceutical and biotechnology sectors, including measures to support the growth of small and medium enterprises (hereinafter "SMEs").

Since BNDES³ (National Bank for Economic and Social Development) has launched a programme to nurture the growth of the Brazilian pharmaceutical industry, so-called Profarma (Support Programme for the Development of the Pharmaceutical Productive Chain), this state-owned bank was also visited and an interview was conducted with public officials from Defarma (Department for Intermediate Chemistry and Pharmaceutical Products). The interview tried to identify the main objectives of Profarma and to collect quantitative data on the various lines of credit offered by this programme.

2. Centralized Procurement, Public Drug Production and Public-Private Partnerships in the Brazilian Health Sector

Procurement can be understood as the process which creates, manages and fulfills contracts relating to the acquisition of goods and to the hiring of contractors or consultants to carry out works or provide services (Owegi and Aligula, 2006: 4; Watermeyer, 2004: 1). In the past few years, procurement has “shifted from being a mere processing task to a management- and knowledge-based activity that supports good governance and enhanced accountability” (Sanchez, 2009: 17). It has, thus, become a strategic government function essential to back up the implementation of development policies and to achieve the country’s economic and social goals (Ladipo *et al.*, 2009: 79; Casals & Associates and Claro & Associates, 2010: 19).

The term centralized procurement is used when the process is conducted by a central body, such as the Ministry of Health, and “all the relevant decisions (what, how and when) to purchase products, whether by competitive tendering procedures or by negotiations, are in the hands” of this central public unit. Conversely, decentralized procurement refers to the delegation of “the power to decide how, what and when to procure” to divisions or local administrations, such as the Secretariat for Health at the state or municipality levels (Dimitri *et al.*, 2006: 48).

In a number of comparisons between centralized and decentralized procurement systems, authors have identified several advantages and disadvantages of each of these systems (OECD, 2000; Dimitri *et al.*, 2006). Among the main advantages of decentralized procurement is its capacity to reduce the scope for large scale corruption, mistakes and overspending (OECD, 2000). Moreover, authors claim that a decentralized procurement agency may have a deeper knowledge of the needs of the local population. In addition, decentralization may increase the efficiency of public expenditure, as the local governments will be able to procure products and services according to the demand, achieving a closer matching between supply and demand. Finally, as decentralized procurement significantly reduces the purchase volume, it may provide a greater opportunity for SMEs to compete for governmental tenders.

However, as discussed below, in the health sector the positive effects of centralized drug

Table 1 Summary of the Main Potential Advantages of Centralized Public Procurement

Impact on Drug Price	Human Resources Specialization	Market Dynamics and Innovation	Institutional Benefits
<ul style="list-style-type: none"> • Better price and quality of procured supplies and services; • Cost reduction through economies of scale; • Avoid duplication costs; • Increased purchasing power of the centralized agency, raising bargaining power; • Facilitates products and services standardization; • Better quality and safety assurance of drugs. 	<ul style="list-style-type: none"> • Increased concentration of procurement expertise; • Better delivery of training; • Better performance management of procurement staff; • Greater standardization of technical requirements, procurement contracts and transactions; • Better knowledge and information sharing among specialists. 	<ul style="list-style-type: none"> • The centralized agency may use its purchasing power to foster innovation in the private sector and induce the path of technological change; • Potential to strengthen domestic firms; • Potential to foster innovation on neglected diseases through PPPs and advance purchase commitment; • Possibility to affect the market structure, by giving important signal to the supply market and pointing the way for development and innovation; • The award of large centralized public contracts is likely to affect the distribution of the market shares of firms. 	<ul style="list-style-type: none"> • Litigations may be concentrated in a limited number of courts; • Greater transparency and measurability of government procurement procedures; • Greater impact on green procurement strategies due to large-scale purchase of environmentally sustainable items; • Improves the capacity to monitor suppliers' performance and prevents opportunism.

Source: Dalpé, 1994; OECD, 2000; Dimitri *et al.*, 2006; Edler and Georgiou, 2007; Albano and Sparro, 2010.

procurement tend to exceed the advantages of decentralization. Table 1 summarizes the main advantages of centralized public procurement highlighted in the literature. These are advantages of centralized procurement in general and, therefore, are not specific to any particular area. They were, however, synthesized and adapted to this present study on the health sector.

Cost reductions is one of the main advantages, which is the result of the high purchasing power of a centralized agency procuring drugs in large volumes. It has been recently reported in the media, for instance, that the Ministry of Health in Brazil negotiated a reduction of 51% in the price of Gleevec (*imatinib mesilate*), a drug produced by Novartis for the treatment of leukemia and other types of cancer, resulting in savings of over US\$ 230 million in two and a half years (Ministério da Saúde, 2010). It was stated during the interviews that the procurement for this drug was once decentralized, but the Ministry of Health decided to recentralize it as a way to increase the bargaining power for price reduction negotiations.

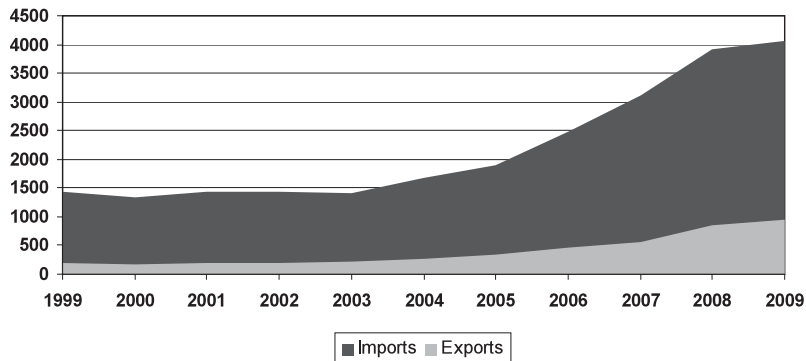
A number of similar examples of considerable drug price reductions can be pointed out in the Brazilian HIV/AIDS programme. Drug procurement under this programme has been totally

centralized in the Ministry of Health. This increases the bargaining power of the central government due to the large volume of ARVs procured. In 2005, for instance, the Brazilian government threatened to issue a compulsory license⁴ for *Lopinavir/Ritonavir*, an ARV which accounts for a large share of the Ministry of Health's expenditure. The government withdrew the threat after negotiating a 50% price reduction for the drug. The Brazilian central government also succeeded in reducing its expenditure by fostering public ARV production in public laboratories and actively endorsing the use of generic drugs.⁵ Historically, the average price reduction for patent protected ARVs was 50%, while for ARVs produced by public laboratories or available in generic form the average was 87% (Rossi, 2008). Specialists contend that the economic benefits of the HIV/AIDS programme go far beyond drug price reduction. It was estimated that the Brazilian government saved over US\$ 2 billion from 1997 to 2003 by reducing the number of patients in need of hospitalization or intensive care (Grangeiro *et al.*, 2006: 62).

According to Nunn *et al.* (2007: 1805), "together, Brazil's policy of providing universal access to treatment, producing generic ARVs, and negotiating prices for patented drugs have been referred to as the 'Brazilian model' for AIDS treatment". It is, therefore, widely recognized in the literature that generic ARV production by public laboratories associated with successful price negotiation processes undertaken by the Ministry of Health to reduce the costs of patented ARVs were pivotal for the effectiveness of the Brazilian HIV/AIDS programme (WHO, 2004a: 66). Additionally, the threat of issuing a compulsory license was highly relevant for persuading transnational pharmaceutical firms to reduce their prices (Galvão, 2002: 1862). Nevertheless, as already mentioned, the role played by centralized public procurement was also fundamental. By universalizing the access to public and free AIDS treatment and centralizing the acquisition of all ARVs in the Ministry of Health, the Brazilian government greatly increased its bargaining power in negotiations with large transnational pharmaceutical firms, due to the substantial quantity of drugs purchased in bulk. As a result of centralized procurement, transnational firms had no option but to negotiate with the Ministry of Health in order to gain access to the Brazilian market.

Centralized procurement also concentrates skilled human resources and facilitates market analysts and drug experts training (OECD, 2000; Albano and Sparro, 2010). This may help tracking down drug prices in the international market to assist in negotiations and to improve cost-benefit analysis on the financial impact of centralizing the procurement of specific drugs. In addition, the concentration of experts may facilitate assessing the desirability of including newly developed drugs into the public health system. In Brazil, this assessment is conducted by the Commission of Health Technology Incorporation (CITEC) of the Ministry of Health. In the specific case of HIV/AIDS, experts are constantly monitoring the market to evaluate the possibility of reducing the unit cost of procured ARVs and to analyze the urgency of substituting first-generation to second-generation drugs.

On top of that, centralized procurement can be used to foster innovation and stimulate R & D

Figure 1 Imports and Exports of Drugs in Brazil (US\$ million)

Source: Abiquif, 2010.

activity for the development of new drugs (Dalpé, 1994; Edler and Georghiou, 2007). Webber and Kremer (2001: 736–738) argue that “enlarging the value of the market for medicines and vaccines through, for example, global purchase funds, is a critical step towards stimulating R & D in [neglected infectious diseases]”. As these diseases affect mostly poor households in developing countries, “commercial markets are small” and “individual purchasing power is severely limited”. Furthermore, “R & D costs for all diseases are high” and, therefore, “returns will not cover investments” in developing new drugs for neglected diseases. Thus, it may not be of interest for private firms to invest in this segment, unless they are given real profit opportunities. Advance purchase commitment can function as a guarantee that private investors will have an assured outlet for their products in case they develop a new drug for a neglected disease is developed. The purchase commitment, however, “would have to be for a large enough quantity of the product to create a market of sufficient value to overcome the ‘inadequate market value’-barrier to research investments”. Centralized public procurement is pivotal for ensuring this large quantity through bulk acquisitions.

In 2008, the Ministry of Health started encouraging PPPs based on technology transfer using a number of public laboratories. The public sector in Brazil has a central role in drug production through over 17 state-owned laboratories. As already mentioned, however, drug production in these public facilities is restricted to formulations. It is estimated that 80 to 90% of the APIs used in Brazil are imported, mainly from China and India (Cytrynowicz, 2007: 173), which greatly contributes for the significant trade deficit in the Brazilian health sector (Figure 1).

The PPPs are expected to decrease this trade deficit and to reduce the technological backwardness of Brazilian pharmaceutical firms by vertically integrating the manufacturing process of strategic drugs in Brazil. The PPPs, therefore, were designed to improve the capacity of public laboratories in API production and, at the same time, to strengthen domestic pharmaceutical firms. In these partnerships, the private firms will develop their own capacities to produce APIs for strategic

drugs and then transfer the expertise to public laboratories. These are contracts with advance purchase commitment of up to 5 years to encourage large private pharmaceutical firms to engage in collaboration with public laboratories.

In the past, these partnerships have been successfully used for the production of the ARV called *Efavirenz* under demand of the Ministry of Health. Following the Brazilian government decision to issue a compulsory license, the Brazilian firms Cristália, Nortec and Globe started supplying APIs for the production of *Efavirenz* by the public laboratories Farmanguinhos and Lafepe (Pharmaceutical Laboratory of Pernambuco). It is worth mentioning, however, that there was a considerable time lag between the issuing of the compulsory license in May 2007 and the starting up of *Efavirenz* domestic production by Farmanguinhos in March 2009 (Lago and Costa, 2009; Rodrigues and Soler, 2009). It can be expected, therefore, that a significant time will be necessary for positive outcomes to emerge from the newly formed PPPs.

As the Ministry of Health started formally encouraging PPPs from 2008, the contracts are quite recent. It is, therefore, still difficult to evaluate their effectiveness and to observe their outcomes. One of these contracts was signed between the public laboratory Funed (Ezequiel Dias Foundation) and the private domestic firms Nortec and Blanver for the production of *Tenofovir*. A partnership between Cristália and the state-owned firm Hemobrás (Brazilian Company of Blood Products and Biotechnology) will produce the recombinant factor VIII for hemophilia. Cristália is also engaged in another partnership to produce antipsychotic drugs such as *Clozapine* with the public laboratories Nuplam (Center for Research on Food and Medicines) and Lafepe. Partnerships between Brazilian public laboratories and private transnational firms have also been reported, such as the collaboration between Farmanguinhos and the Indian firm Lupin Pharmaceuticals for the production of tuberculostatics (Ministério da Saúde, 2009).

The government can, thus, use its purchasing power to foster R & D for neglected diseases, through advance purchase commitment or by guaranteeing temporary exclusive procurement rights for any private firm that generates a new drug for such type of diseases. In Brazil, the Ministry of Health may further explore such an idea to intensify collaborations between public laboratories, private firms and universities towards more intense R & D activities focused on neglected diseases.

As already mentioned, the literature identifies the difficulty in fostering SMEs as the main disadvantage of centralized procurement (OECD, 2000; Albano and Sparro, 2010). However, interviews conducted at the Ministry of Development, Industry and Foreign Trade reveals that efforts are being made to change the Brazilian legislation so that centralized public procurement may be used to stimulate smaller-sized firms. The proposal is to define a percentage of drugs that will only be supplied by SMEs to SUS. If approved, this initiative will bring positive and significant impacts for these firms, since most of them will greatly expand if the demand for their products were to increase.

In addition, although one of the drawbacks of centralized procurement is said to be its greater

susceptibility to corruption, it is important to bear in mind that in states and municipalities where the private sector is well-developed, the local government may face a stronger pressure from pharmaceutical firms. A number of managers at Iquego alleged that the presence of the third biggest Brazilian pharmaceutical industrial cluster in Anápolis, in the state of Goiás, was a hindrance for negotiations between this public laboratory and the local government, due to unfair business practices by private local firms. In fact, it has been repeatedly argued in the literature that decentralized initiatives may be partially ineffective in face of disproportional power held by local pressure groups (Hutchcroft, 2001).

Finally, it is worth mentioning that there are a number of cases in which decentralized procurement systems have produced positive outcomes in health programmes. One example is the decentralized procurement system in operation in São Paulo, which is the result of a partnership between the Secretariat of Health of this state and Furp (Foundation for Popular Medicine). Furp is a public laboratory created in 1974 and directly linked to the São Paulo local government. This laboratory has reported a consistent average of 1.5 to 2 billion drugs produced per year from 2000 to 2008. One of the main reasons for this good performance is the *Dose Certa* Programme, created by the local government and implemented by Furp. From 2005 to 2008, an average of over 1.5 billion drugs a year were distributed to several municipalities in São Paulo by the *Dose Certa* Programme, most of which produced by Furp (Furp, 2009: 6, 11). It is interesting to add that São Paulo state hosts the largest number of private pharmaceutical firms in Brazil, but this does not seem to have hindered the implementation of the programme.

However, one should note that São Paulo is the richest and most populous state in the country, with 41 million inhabitants (IBGE, 2010). It can thus be expected that the Secretariat of Health at the state level will have a well-developed structure, in many ways similar to a large centralized procurement agency. There are, however, a number of states in Brazil, particularly in the North region, with a population of less than 500 thousand people, scattered in a large area and sometimes residing in inhospitable places. During the interviews with the logistics manager of Iquego, it was reported that this laboratory delivers drugs, sometimes in small lots, to remote areas within the Amazon rainforest. For these deliveries, the truck had to be loaded into a ferry boat to cross the Solimões River and the whole trip would take approximately 30 days.

Furthermore, in the case of São Paulo, the local government was proactive in creating a local health programme and keen in establishing a partnership with a public laboratory. Several interviewed managers in Iquego voiced complaints about the lack of support from the Goiás local government. Although Iquego is actually directly linked to and controlled by the Goiás state, it was reported that most of the local municipalities procure drugs from private firms rather than from this public laboratory. As a result, the majority of drugs produced by Iquego are sold to the Ministry of Health or to municipalities located in other states.

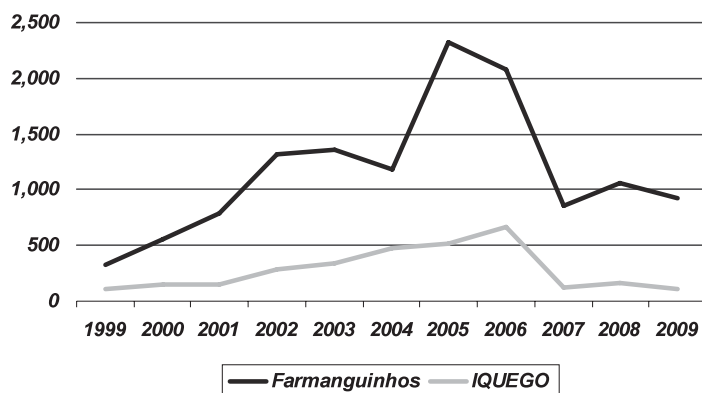
Therefore, although for specific cases decentralized procurement systems may bring positive results, large regional disparities in terms of socio-economic development, infrastructure, human resources and population provides yet another rationale for the use of centralized procurement in the health sector in the Brazilian context.

3. Main Constraints of the Current Brazilian Policy

Public laboratories are central in the current policy adopted by the Ministry of Health. The rationale is that centralized public procurement provides a stable and secure outlet for drugs produced by public laboratories. These public facilities will benefit from economies of scale and may reduce government expenditure on medicines. Centralized procurement also increases the Ministry of Health purchasing power, as the government concentrates the demand for drugs that would otherwise be pulverized in the Secretariat for Health at states and municipalities levels. By using both centralized procurement and public production of drugs, the Ministry of Health will have a greater bargaining power in negotiations for price reduction with transnational pharmaceutical firms. In addition, public laboratories may be used to nurture innovation in the private sector through PPPs and may engage in R & D activities focused on neglected diseases.

However, a significant reduction in production levels observed in public laboratories tends to show a lack of alignment between the Ministry of Health's priorities and the activities of these public facilities. The production of Farmanguinhos and Iquego are displayed in Figure 2. As aforementioned, Farmanguinhos is one of the biggest public laboratories in Brazil and is directly linked to the Ministry of Health while Iquego is a large public laboratory controlled by the government of Goiás. There are over 17 public laboratories in Brazil engaged in drug production and, in June 2009, these facilities

Figure 2 Production of Farmanguinhos and Iquego (Million Units)



Source: Chagnon, 2007; and data collected by the author during fieldwork.

reported over 60% of idle production capacity (Agência Câmara, 2009). The examples of Farmanguinhos and Iquego illustrate this problem of idle production capacity observed from the mid-2000s in most of these public laboratories.

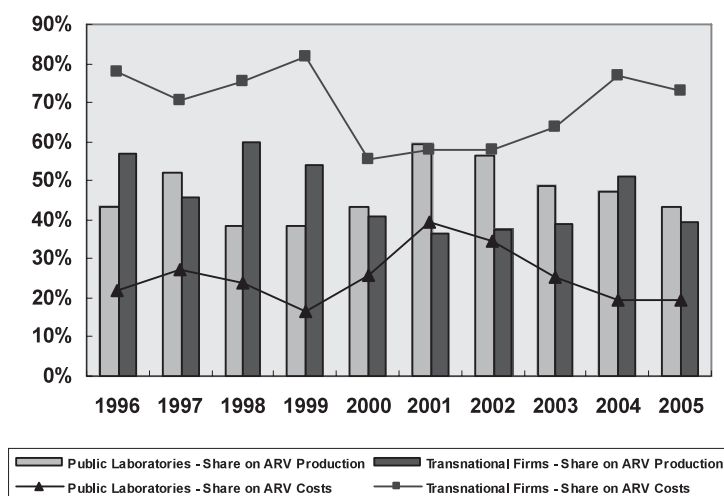
The sharp decrease in production observed from 2006 was mainly caused by procurement decentralization of major public health programmes from the Ministry of Health to the Secretariat for Health of states and municipalities. As the Ministry of Health was the main buyer of drugs from Iquego and Farmanguinhos, this sudden change in these programmes has had a negative impact on public laboratories' productivity. Iquego, for instance, was a large producer of drugs for diabetes and high-blood pressure for the central government. Until 2006, centralized public procurement has assured a stable outlet for its products. After the decentralization, however, the Secretariat for Health of each state and municipality has the discretion to decide whether to procure from public laboratories or private firms.

One should note, however, that public laboratories were not designed to compete with the private sector. They are not profit-oriented institutions and are supposed to facilitate the access of the population to essential medication. Their R & D activities are also centered on filling the gap of the private sector on niches such as neglected diseases and other fields which are relevant for major public health programmes. These facilities are not meant to struggle for market share with private firm or to promote irrational drug use.

The production decrease of public laboratories is inconsistent with the increasing demand for essential drugs in SUS. This tends to evidence the mismatch between the Ministry of Health's strategy and the activities of these public facilities. The lack of alignment between the Ministry's priorities and public laboratories' R & D and production activities may jeopardize the successfulness of public health programmes. A closer interaction between the Ministry of Health and these public facilities is of utmost importance to avoid overlapping activities between public and private pharmaceutical laboratories and to ensure that public laboratories' production and R & D initiatives are in line with the needs of the Brazilian population. A more intense communication process will also result in a more clear definition of the main attributions for each laboratory. As already mentioned, there are over 17 public facilities in Brazil and the Ministry of Health should take the leading role in clearly defining the types of drugs that each of these facilities should focus upon and which geographical regions they will supply. This would avoid overlapping production activities and may reduce costs associated with deliveries in small lots to remote regions by grouping deliveries to the same area.

Another bottleneck observed in the Brazilian pharmaceutical industry that may endanger the effectiveness of the Ministry of Health's Policies is technology backwardness. The HIV/AIDS programme, for instance, is portrayed in the literature as a highly successful initiative of the Brazilian government (Cassier and Correa, 2007; Flynn, 2008), but faces challenges that may put at risk the

Figure 3 Share of ARV Production and Costs in Brazil: Transnational Firms versus Public laboratories



Note: Data regarding private domestic firms were not included as they were responsible for an average of 5.96% of ARV production and 5.44% of ARV costs during this period.

Source: Rossi, 2008.

sustainable delivery of free and up-to-dated ARVs in the long run. Although the public laboratories are responsible for a considerable production share of ARVs purchased by the Ministry of Health, ARVs produced by foreign firms are more significant when it comes to the impact on the Ministry's budget. In 2005, although public laboratories produced 43.1% of the ARVs available in the country, these drugs corresponded to only 19.6% of the total costs (Figure 3). Conversely, while foreign firms produced 39.5% of these drugs, they accounted for 72.8% of the Ministry of Health's expenditure. Public laboratories produce mainly first-generation ARVs, which are not under patent protection and are low value-added if compared to second-generation ones. This explains the high prices paid for drugs manufactured by foreign firms.

The Brazilian HIV/AIDS programme is based on centralized procurement of ARVs by the Ministry of Health, which gives a great bargaining power to the government in negotiating price reductions. The Brazilian Constitution considers health as a common good and the government has the duty to provide free and universal access to the health system. Infra-constitutional legislation (Law n. 9,313, enacted in November 13, 1996) rules that ARVs should be distributed for free by SUS. In Brazil, therefore, the government is the only purchaser of ARVs, which creates a monopsonic market. This centralized procurement system also facilitated the process of issuing a compulsory license for Efavirenz. Nonetheless, if Brazilian public laboratories or domestic private firms do not have the technical capacity to produce second-generation ARVs, this bargaining power will be greatly reduced. This demonstrates the relevance of developing a strong and technologically advanced

domestic pharmaceutical industry in Brazil and the importance of fostering innovation through centralized procurement and PPPs.

As a final consideration, it is important to keep in mind that, in addition to implementing initiatives focused on nurturing the domestic private sector through PPPs and using centralized public procurement, the Brazilian government also needs to increase the efficiency of policies designed to provide direct financial assistance to private firms. It is true that the government has recognized the pharmaceutical industry as strategic in two recent industrial policies, PITCE (Industrial, Technological and Foreign Trade Policy) and PDP (Production Development Policy), respectively in 2003 and 2008. Moreover, in 2004, BNDES launched Profarma, a programme aimed at providing financial support for modernizing Brazilian pharmaceutical firms and to stimulate R & D activities (Brazil, 2003; Brazil, 2008, Capanema, 2006: 205).

However, the gap in terms of R & D investment and innovation capacity between Brazil and the biggest pharmaceutical firms in the world is still enormous. For instance, in 2009, Laboratório Cristália, one of the leading firms in the Brazilian pharmaceutical industry, invested 6% of its revenue in R & D, which corresponds to approximately US\$ 17 million. In the same year, main pharmaceutical firms in Europe and the United States, such as Roche, Pfizer, Novartis, Sanofi-Aventis and GlaxoSmithKline, all recorded investments of over US\$ 5 billion in R & D (JRC, 2010).

According to data collected during the interviews, the total amount spent by BNDES from 2004 to 2007 under the Profarma programme to encourage domestic pharmaceutical firms in undertaking R & D activities was only US\$ 64.9 million. By 2010, this amount has greatly increased to US\$ 258.1 million, but such financial resources still seem to be insufficient to generate new drug development. In India, which is an emerging economy with a strong pharmaceutical industrial sector, largest firms such as Sun Pharmaceutical Industries, Cipla and Matrix Laboratories invested over US\$ 40 million in R & D in 2009, and the top investor in R & D, Dr. Reddy's, spent over US\$ 80 million (JRC, 2010).

Hence, although the pharmaceutical industry was considered strategic in recent industrial policies since the early 2000s, it is questionable whether the initiatives undertaken by the government will be sufficient to nurture the growth of this sector, especially regarding the amount of expenditure in R & D which is necessary to foster new drug development.

Conclusion

This paper examined how centralized procurement may be used to nurture the Brazilian pharmaceutical industry and to improve the efficiency of public health programmes. By aligning centralized procurement and public drug production, the Ministry of Health is trying to foster R & D initiatives on strategic drugs and to promote PPPs in order to create a vertically integrated domestic pharmaceutical industry.

However, in order for this governmental policy to be successful, a closer pattern of interaction between the Ministry of Health and public laboratories is necessary, so that these public facilities may function according to the Ministry's main priorities and are not negatively affected by sudden changes in public health policies.

Three key lessons can thus be drawn from this study:

1. The Brazilian experience shows that centralized procurement in the Health Sector can be effectively used to: (i) significantly reduce drug prices by increasing the bargaining power of the Ministry of Health in price negotiations; and (ii) to stimulate innovation and R & D activities through PPPs and advance purchase commitment.

2. A closer interaction is necessary between the Ministry of Health and the public laboratories to align the Ministry's main priorities to the production activities of these public facilities in order to avoid idle production capacity and to improve the quality of health care delivery to the population.

3. Technology backwardness is a serious threat for the sustainability of public health programmes as it reduces the domestic capacity to produce up-to-date drugs and considerably decreases the bargaining power of the Ministry of Health in negotiations for price reductions and technology transfer.

These lessons are also relevant for other developing countries trying to increase access to essential medication. One topic discussed during the interviews, which has also been widely reported in the media, is that Farmanguinhos has signed a cooperation agreement with the government of Mozambique for the construction of a laboratory for the production of ARVs in this African country. Due to the high incidence of HIV/AIDS in Africa, estimated in over 23 million infected people in 2003 (UNAIDS, 2004: 10), the findings highlighted in this paper regarding the use of centralized public procurement and public drug production to nurture the pharmaceutical industry may be used to address the problem of insufficient ARVs for the poor in the region.

In India, public laboratories have played an important role in boosting the industrial development of the domestic pharmaceutical industry. They have, however, largely reduced its activities as domestic firms have increased their production and R & D capacities (Mani, 2006: 26). Nowadays, however, although the Indian pharmaceutical industry is one of the most advanced among the emerging economies, access to essential medication is still a critical problem in the country, as an estimated 499–649 million people (50 to 60% of the population) do not have regular access (WHO, 2004b: 62–63). Discussions about revitalizing the state-owned laboratories to strengthen centralized public drug procurement have recently emerged in the literature and political scene. The discussions presented in this paper may be relevant for the Indian context by providing insights on the use of centralized public procurement as a way to persuade the already existing strong private pharmaceutical sector to work in benefit of the most deprived sections of the local population. There have been successful initiatives from some local governments in Indian, the most prominent being Tamil Nadu state drug public procurement (Sengupta *et al.*, 2008: 11), but similar initiatives are still

mostly absent on a national scale.

Notes

- 1 For instance, Daiichi Sankyo acquired Ranbaxy Laboratories in June 2008 for US\$ 4.6 billion (The Economic Times, 2010); Abbot Laboratories bought Piramal Healthcare in May 2010 for US\$ 3.7 billion (Timmons, 2010); and Sanofi-Aventis took over Shantha Biotechnics in July 2009 for US\$ 783 billion (The Financial Express, 2009).
- 2 SUS (*Sistema Único de Saúde* or Unified Health System) is the Brazilian public health care system created in 1988 as a result of the Constitutional provision in Article 196, which states that “health is a right of all and a duty of the State and shall be guaranteed by means of social and economic policies aimed at reducing the risk of illness and other hazards and at the universal and equal access to actions and services for its promotion, protection and recovery” (Brazil, 2010). It is estimated that approximately 120 million people, or 70% of the Brazilian population, rely on SUS for health care assistance (Marques, 1999: 17). The Brazilian constitution also stipulates that SUS will have a decentralized structure and will be financed “with funds from the social welfare budget of the Union, the states, the Federal District and the municipalities, as well as from other sources” (Article 198, Paragraph 1). In 2006, the expenditure in health of the central, state and municipal governments was US\$ 50 billion, which accounted for 3.6% of the country’s GDP (Ministério da Saúde, 2011). In the same year, the Ministry of Health spent US\$ 2.6 billion in drug acquisition for SUS main health programmes (Moysés Junior, 2010).
- 3 BNDES (*Banco Nacional de Desenvolvimento Econômico e Social* or National Bank for Economic and Social Development) was created in 1952 with the role of financing infrastructure and industrial development and it has historically played an important role in supporting industrial growth in Brazil.
- 4 Compulsory licensing is one of the flexibilities offered by the TRIPS (Trade Related Aspects of Intellectual Property Rights) Agreement of the WTO. According to this provision, a member country may allow a third party to pursue local production of a patented drug “without the patent holder’s permit, if justified in the public interest” (Cohen *et al.*, 2005). The patent holder, however, is entitled to receive royalty payments. This flexibility is based on the principle that the “TRIPS Agreement does not and should not prevent Members from taking measures to protect public health”, which is recognized in the WTO Declaration on the TRIPS Agreement and Public Health, adopted on November 14, 2001 (WTO, 2001; Kerry and Lee, 2007).
- 5 Generic drugs are copies of off-patent medicines, which are considered interchangeable with the correspondent brand-name drugs after bioequivalence and bioavailability testing. Such tests ensure that the generic drugs have the same chemical composition, quality and stability of brand-name drugs and guarantee that they will have the same effects on the human body. The Brazilian government decided to support the development of a generics market as a way to improve the population access to essential drugs and to enhance the policy of free medication distribution (Lobo, 2009: 345). After the Law 9,787 was enacted on February 10, 1999, regulating generic drugs production in Brazil, these drugs were imported until domestic firms developed their technical capacity to produce them.

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