

“Farmácia Popular do Brasil” Program: characterization and evolution between 2004 and 2012

Rondineli Mendes da Silva ¹
Rosangela Caetano ²

Abstract *The “Farmácia Popular do Brasil” Program (PFPB) aims to improve access to medicines, offering subsidized products. It is structured in an arrangement involving public and private sectors. The paper described the organization and expansion of the PFPB and examined the reference price (RP) of the medicines paid by the government, between 2004 and 2012. It is an exploratory study of quantitative and qualitative approach, developed from the literature review and analysis of public documents. Quantitative data were collected from the Ministry of Health and Electronic System of Citizens Information Services. The PFPB is organized in two delivery models: public owned facilities (Rede Própria) and accredited private retail pharmacies (Aqui Tem Farmácia Popular - ATFP). The ATFP has allowed its own expansion, from 2006. Antihypertensives, antidiabetics and antiasthmatics were exempt from copayment, since 2011. The expansion of the ATFP Program was significant, for facilities and covered municipalities, 750% and 528%, respectively. The RP was reduced by 33.6% on average (ranging from 23-52%) for medicines available since the beginning of the ATFP. The expansion was performed with the actions hitherto unprecedented, as copayment and accreditation of private retail pharmacies.*

Key words *Pharmaceutical services, National drugs policy, Government programs*

¹ Escola Nacional de Saúde Pública Sérgio Arouca, Fiocruz. R. Leopoldo Bulhões 1480, Manguinhos. 21041-210 Rio de Janeiro RJ Brasil. rondineli.mendes@gmail.com

² Instituto de Medicina Social, Universidade do Estado do Rio de Janeiro.

Introduction

Access to medicines is one of the most important social challenges for all governments, especially for those countries with systems of universal access¹.

In Brazil, the difficulties of accessing and using medicines have been highlighted. Often, essential medicines are not available in the public health services to the detriment of citizens who depend on and need these products^{2,3}.

Spending on medicines represents the highest portion of health expenditures in family budgets, especially for low-income families⁴. In the 2008-2009 Brazilian household budget survey (POF, Portuguese acronym), of the those families that purchased medicines, the poorest family spent 8.5% of their income on medicines, in contrast to less than 2% by the top income decile⁵.

Starting from the end of 1990's, the National Medicines Policy (PNM) and the National Policy on Pharmaceutical Services (PNAF) have established policy guidelines that focus on improving access and rational use of medicines in the public health system – Unified Health System (SUS)⁶.

Specific programs have been established in Brazil with the objective of promoting access to essential medicines to the population via public pharmacies available within SUS's health care facilities⁷. However, there remain difficulties in public supply and evidence of great disparities across income levels in the amount of household budget used for medicines expenditures⁵. These problems led the Ministry of Health (MoH) to introduce in 2004, for the first time, a user copayment scheme. Initially, the "*Farmácia Popular do Brasil*" Program (PFPPB) was established through a public owned pharmacy network, and was subsequently expanded through partnerships with the retail private pharmacies. Further changes occurred in 2011 with the introduction of exemptions from copayment for specific medicines. The Program (PFPPB) has been one of the main policies of the federal government⁸ and is one of the main cornerstones of the Brazilian Pharmaceutical Service Policy^{9,10}.

The objectives of this paper are to describe the organization of the "*Farmácia Popular do Brasil*" Program and its different delivery models, its coverage and expansion between 2004 and 2012, and to analyze the reference prices of the medicines included in the Program.

Methods

It is an exploratory study using quantitative and qualitative approaches.

A bibliography and documentation review was undertaken of the various methods for provision of medicines in Brazil, in order to identify the concepts, historical background and the development over time of the PFPPB's different delivery models.

The main bibliographic sources were Medline and Lilacs databases and repository of thesis of academic institutions. The timeframe for the research was from January 2003 to January 2013, using keywords in Portuguese "assistência farmacêutica" ("pharmaceutical service"), "farmácia popular", "copagamento" ("copayment") and "modelos de provisão de medicamentos" ("medicines delivery models").

A survey and analysis of public documents including laws, ordinances, internal regulations and other specific documents related to the PFPPB was also performed. This involved: (1) direct search of the dedicated PFPPB¹¹ section of the MoH's website, which provides access to information such as the main rules and guidelines; (2) search in the legislation system of the MoH, named "*Saúde Legis*", which assembled the normative acts of the SUS in the federal level¹² using keyword "farmácia popular"; (3) searches in the Virtual Health Library (BVS-MS), covering the same period to complement other documents on the creation, technical guidelines and medicines list of the PFPPB¹³. In addition, analysis of management reports at Oswaldo Cruz Foundation (Fiocruz) were performed in order to identify elements of the early years (2004 and 2005) of the Program and other references related to the public owned facilities (*Rede Própria*)^{14,15} which were first established by Fiocruz.

The PFPPB was analyzed according to six categories: (1) management and implementation; (2) structuring and operation; (3) medicines and health products available; (4) medical prescription; (5) price and payments to pharmacies; (6) control and audit.

The expansion of the Program in the period was investigated directly on the MoH website¹¹ and in via SAGE database (Room to Support Strategic Management – *Sala de Apoio a Gestão Estratégica*). SAGE is a database for monitoring the priority health actions of the Brazilian federal government, such as PFPPB¹⁶.

Information on the number of users over

time and by location was obtained from responses to information requests sent to Federal and public institutions under the Electronic System of Citizen Information Services (e-SIC) and the Access to Information Act¹⁷.

Quantitative information on the number of pharmacies, municipalities covered and users attended by the two delivery models of the PFPB for the period 2004 to 2012 was organized by year.

The Reference Price (RP) is a price benchmark, for each pharmaceutical unit established by the MoH, for payments to accredited private sector pharmacies. An analysis of the RP was based on a review of the regulations made for the PFPB and restricted to products available since the beginning of the Program.

Results

Evolution of the “Farmácia Popular do Brasil” Program

The PFPB was first proposed in 2002 as part of the election campaign for the Brazilian presidency⁸. It was implemented in 2004 with the strategic objective of expanding access to medicines through a copayment scheme. The payments would be shared between the users and the MoH with the aim of reducing the impact of medicines pricing on families' budgets.

In relation to the selection of medicines, the PFPB aims to improve access to medicines for the treatment of the most prevalent diseases. The majority of the products covered by the PFPB are on the national essential medicines list¹⁸ (RENAME). However, there are some that were not part of current RENAME (2013), for example atenolol 25mg¹⁹.

The management of the Program was always the responsibility of the MoH's Department of Pharmaceutical Services (DAF/MoH). Initially, the Program was based on a public pharmacy network managed by Fiocruz. From 2006, the Program was expanded to accredited private retail pharmacies. Currently, the Program is regulated by MoH ordinance 971/2012²⁰ and it is based on two delivery models – public owned facilities (*Rede Própria*) and accredited private retail pharmacies (“*Aqui Tem Farmácia Popular*” - ATFP).

In 2011, medicines for hypertension and diabetes were made free of charge for users by the removal of users' copayment fees in both the public and private PFPB pharmacies (*Rede Própria* and ATFP). This change was presented as a “campaign” called “Health is Priceless” (“*Saúde Não Tem Preço*”). In 2012, antiasthmatics medicines were also exempted from user copayment fees. The remaining medicines provided by PFPB pharmacies still require copayment.

Delivery Model based on Publicly Owned Facilities (*Rede Própria*)

The first phase of the Program was the creation of a network of publicly owned pharmacies by the Oswaldo Cruz Foundation. Partnerships with municipalities, states and public education and philanthropic institutions were developed by Fiocruz aimed at expanding this model. Fiocruz retains the management role of the network, providing operational support to the pharmacies, professional training and operating procedures for procurement and tender processes. In addition, it is responsible for the central storage and logistic supply of the medicines to pharmacies.

The administrative management including operation of the facilities, recruitment human resources, inventory management of medicines, supplies and computational support, as well as building maintenance, furniture and equipment is the responsibility of the pharmacies involved in the Program. The activities of the pharmacies are however standardized, seeking to guarantee uniformity of actions and primarily focused on the management of inventory, list of medicines, equipment and materials, employee uniforms and service to users.

The list of medicines available in the *Rede Própria* is currently composed of 112 products, including various therapeutic classes and male condoms. The medicines are dispensed after payment by users of a copayment fee that reflects the costs of production or acquisition, distribution and dispensing, which are aggregated to create the Dispensing Price. The dispensing price is set by the Program's Management Council (MoH and Fiocruz) and applies for every product in all *Rede Própria*. According to the MoH, the price for this delivery model is different than in a retail model, because profits are not the goal in the Program and are not the source of funds for the maintenance of the facilities²¹.

Delivery Model based on accredited private retail pharmacies - *Aqui Tem Farmácia Popular*

From 2006, the PFPB expanded through partnerships with accredited private retail pharmacies. This model is known as “*Aqui Tem Farmácia Popular*” (ATFP). The accreditation system is based on a request for registration from a private retail pharmacy which has to show compliance with the relevant rules, by provision of financial and health documentation. There is no requirements related to geographic location or population density^{19,22}.

It is mandatory for participating pharmacies to display visual identification of accreditation to the Program, such as the use of specific logos²³.

The ATFP list of medicines is much smaller than that of the *Rede Própria*, although it has grown with the entry of various products, starting in 2006 with the addition of antihypertensive and antidiabetic agents. The following year contraceptives were added and, in 2009, three more presentations of NPH insulin. Against the background of H1N1 influenza, oseltamivir phosphate was incorporated in February 2010. In the same year, four presentations of regular insulin and simvastatin (10, 20 and 30 mg) were also added. New pharmacological classes for treatment of asthma, rhinitis, glaucoma, parkinson's disease and osteoporosis, and more one anti-hypertensive (losartan) and incontinence pads. In 2011, a new antidiabetic was incorporated. Currently, the list of ATFP Program has 41 drugs²⁰. Chart 1 presents all medicines currently available at ATFP with periods of incorporation and indications.

Where copayment applies in the ATFP, the MoH will pay up to 90% of the reference price (RP) and the difference is paid by the user. The system seeks to preference the lowest price, therefore if the retail price of the product is lower than the RP, the government will only pay 90% of this retail price.

From 2011, under the campaign slogan “Health is Priceless” (“*Saúde Não Tem Preço*”) user payment fees were removed from some medicines, initially for antihypertensive and antidiabetic medicines and later for asthma treatments. In these cases, the total RP was paid by the MoH to the accredited facilities.

The PFPB is regulated under the MoH ordinance 971/2012²⁰. This ordinance contains explicit rules regarding the procedures for the sale and dispensing of medicines through the Program. These require: (1) the user to provide

an official photo ID and tax number (CPF); (2) a prescription dated, signed and stamped by a doctor and containing the doctor's Medical Council registration number, the full name and address of the patient and the address of the health facility; (3) the prescription is valid for 120 days from the date of issue (for contraceptives, 12 months). A prescription, medical report or medical certificate is required for the purchase of incontinence pads. For patients with disabilities provided for in Brazilian law (under articles 3rd and 4th of the Brazilian Civil Code), for example less than 16 years old, patients with disabling illnesses or mental health issues, the physical presence of the prescription holder is not required.

From 2010, measures were adopted to ensure greater control and supervision of the ATFP after several complaints of fraud and errors, such as sales to deceased persons and home delivery²⁴. The registration of patients and delivery of medicines outside the accredited facilities was prohibited. Pharmacies are required to file copies of prescriptions, invoices, purchase and sales tax receipts for five years. There are also other control elements through a sales authorization system with the possibility of fines for any irregularities or non-compliance with requirements and inspections by the SUS Audit Department.

The MoH makes payments directly to the accredited retail pharmacies in ATFP, which are first checked against the dispensing information contained in the Program's electronic authorization system (“*Sistema Autorizador DATASUS*”).

Chart 2 summarizes the main features of the PFPB in its two delivery models, organized in six categories.

Coverage and Expansion of *Farmácia Popular do Brasil* Program

There was a significant increase in the number of pharmacies and municipalities covered by the *Rede Própria* until 2007, with a subsequent drop in the rate of growth. Between 2005 and 2008, there was a significant expansion in the number of users of the *Rede Própria*, which remained relatively stable in the range of 11 million users (Table 1).

In relation to the geographical distribution of the *Rede Própria*, approximately two-thirds of the total facilities in 2012 were in the Southeast (34.8 %) and Northeast (34.4 %), followed by the North (12.7 %), South (11.7 %) and Midwest (6.4 %). São Paulo was the state with the largest number of establishments, totaling 90 pharmacies.

Chart 1. Medicine list and incorporation period in ATFP.

Period	Main Indication	Medicines
March/2006	Hipertension	<ul style="list-style-type: none"> • Atenolol 25 mg tab. • Captopril 25 mg tab. • Propranolol hydrochloride 40 mg tab. • Hydrochlorothiazide 25 mg tab. • Enalapril maleate 10 mg tab.
	Diabetes	<ul style="list-style-type: none"> • Metformin hydrochloride 850 mg e 500 mg tab. • Glibenclamide 5 mg tab. • Insulin human (insulin isophane human) 100 units/mL inj. vials 10 mL
June/2007	Contraception	<ul style="list-style-type: none"> • Medroxyprogesterone acetate 150 mg/1mL inj. • Ethinylestradiol/Levonorgestrel 0,03 mg + 0,15 mg tab. • Norethisterone 0,35 mg tab. • Estradiol valerate/Norethisterone enantate 50 mg + 5 mg/mL inj. vials
April/2009	Diabetes	<ul style="list-style-type: none"> • Insulin human (insulin isophane human) 100 units/mL inj. vials 5, 3 and 1,5 mL
February/2010	Influenza A (H1N1)	<ul style="list-style-type: none"> • Oseltamivir phosphate 30 mg, 45 mg and 75 mg capsules
April/2010	Diabetes	<ul style="list-style-type: none"> • Insulin regular human 100 units/ml inj. vials 10, 5, 3 and 1,5 mL
	Dyslipidemia	<ul style="list-style-type: none"> • Simvastatin 10 mg, 20 mg and 40 mg tab.
October/2010	Hipertension	<ul style="list-style-type: none"> • Losartan potassium 50 mg tab.
	Rhinitis	<ul style="list-style-type: none"> • Budesonide 32 mcg and 50 mcg
	Asthma	<ul style="list-style-type: none"> • Ipratropium Bromide 0,02mg/dose inhaler • Ipratropium Bromide 0,25mg/mL nebulaser liquid vials • Beclomethasone dipropionate 200 mcg/dose powder inhaler • Beclomethasone dipropionate 200 mcg/dose inhaler • Beclomethasone dipropionate 250 mcg/dose inhaler • Beclomethasone dipropionate 50 mcg/dose inhaler • Salbutamol sulfate (Albuterol) 100 mcg/dose inhaler • Salbutamol sulfate (Albuterol) 5 mg/mL nebulaser liquid vials • Carbidopa 25 mg/Levodopa 250 mg tab.
	Parkinson's Disease	<ul style="list-style-type: none"> • Benserazida hydrochloride 25 mg/Levodopa 100 mg tab.
	Osteoporosis	<ul style="list-style-type: none"> • Alendronate sodium 70 mg tab.
	Glaucoma	<ul style="list-style-type: none"> • Timolol maleate 2,5 mg/mL and 5 mg/mL
February/2011	Diabetes	<ul style="list-style-type: none"> • Metformin hydrochloride slow release 500 mg tab.

Inj. - injectable, mcg - microgram, mg - milligram, mL - milliliter, tab. - tablet

The numbers in relation to the growth of the private pharmacy ATPF Program are more significant (Graph 1). In six years, the ATPF Program grew by 750%, expanding from 2,955 to 25,122 pharmacies. The coverage of municipalities also increased, from 594 to 3,730 municipalities (an increase of 528%). There was also strong growth in the number of users, with an increase of 2,617%.

Since the beginning of the ATPF, the Southeast region has been the main region for coverage and expansion of facilities. According to the MoH, between 2006 and 2011, this region accounted for more than 50% of the total pharmacies accredited. In 2012, the Southeast and South accounted for 49.5% and 27.2%, respectively, followed by Northeast (11.0%), Midwest (9.6%) and North (2.8%).

Reference Price changes

Each medicine included in the ATPF has a reference price (RP) established by the MoH, which is valid for the whole of Brazil, and serves as basis for payments made to accredited private pharmacies.

The reference price is a ceiling price for a medicine sold under ATPF. The MoH will pay up to 90% of the RP of a pharmaceutical unit. The user copayment is the remaining 10%. If the retail price is lower than the RP, then the lowest

price prevails and the MoH only pays 90% of this lower retail price.

The Reference Price is calculated in stages, and includes inputs such as: the ex-factory price approved by the Drug Market Regulation Chamber of National Health Surveillance Agency (“*Câmara de Regulação do Mercado de Medicamentos*” – CMED / “*Agência Nacional de Vigilância Sanitária*” - ANVISA); sales revenues according to the Agency; sales volume and an average discount applied to the respective medicines exfactory price. The reference price is based on the lowest price available from several calculations. More details about these calculations are contained in the MoH Ordinance 491/06²⁵.

A series of ATPF Program Ordinances between 2006 and 2012 altered the value of the RP, although the effect differed between medicines. Based on list medicines available since the beginning of ATPF, the RP was reduced by 33.6% on average (ranging from 23-52%). The first reduction of the RP occurred in 2009, by 24.5% on average. The RP values were maintained until 2010. In the following year there was a new reduction, smaller than the first, by 12.0% on average (Graph 2).

Discussion

Access to medicines is a challenging issue for the Pharmaceutical Service at all government levels in the country. Although advances can be seen, such as an increase in the financing of medicines⁶, there are also difficulties and barriers to access, in which patients are using out-of-pocket payments that negatively affect their income. These challenges served as a justification for the implementation in 2004, by the federal government, of the *Farmácia Popular do Brasil* Program.

The creation and expansion of the PFPB is a significant innovation in the Brazilian Pharmaceutical Service Policy and a key mechanism to achieve the principle of universal access to health care provided by SUS. However, one of the effects is the creation of different methods of medicines provision in the country: (1) free of charge in public pharmacies based on official lists of medicines; (2) copayment in publicly owned pharmacies (*Rede Própria*) of the PFPB based on a defined medicines list; (3) copayment in accredited private retail pharmacies of PFPB (ATFP) based on a defined medicines list; (4) exemptions from copayment in the *Rede Própria* and ATPF pharmacies limited to some medicines; and (5)

Table 1. Number of facilities, municipalities covered and users attended by the publicly owned facilities (Rede Própria) of the “Farmácia Popular do Brasil” Program, between 2006 and 2012.

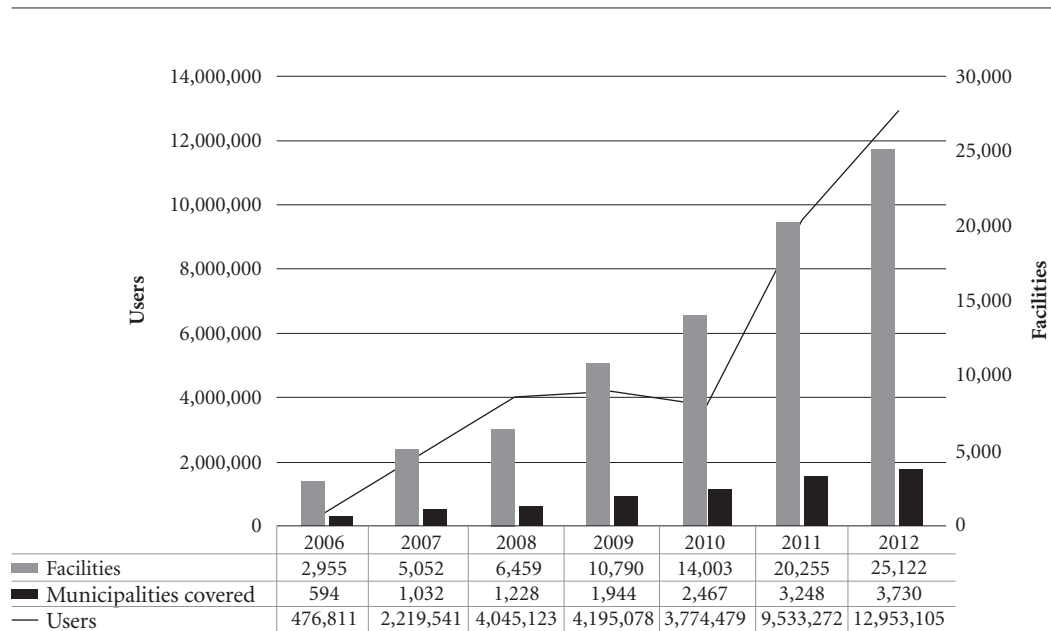
Year	Number of facilities	Municipalities covered	Users attended
2004	27	7	470,133
2005	75	47	2,014,743
2006	259	206	5,972,316
2007	407	321	9,152,340
2008	504	391	10,802,974
2009	530	407	11,467,610
2010	543	420	11,340,850
2011	555	435	11,688,194
2012	558	441	11,730,103

Source: Electronic System of Citizen Information Services (e-SIC) and management reports from Oswaldo Cruz Foundation (Fiocruz) of the 2011 and 2012.

Chart 2. Characteristics of the “Farmácia Popular do Brasil” Program (PFPPB).

Dimensions	Delivery model based on publicly owned facilities – Rede Própria	Delivery model based on accredited private retail pharmacies – Aqui Tem Farmácia Popular	Health is Priceless – Saúde Não Tem Preço
Management and implementation	<ul style="list-style-type: none"> • Management by MoH and Fiocruz • Execution by Fiocruz and expanded through agreements (convênio) with states, municipalities, and other non-profit institutions 	<ul style="list-style-type: none"> • Management only by the MoH • Accreditation of private retail pharmacies by expressions of interest in business, requires adequate financial and health documentation (regulatory health authorities) 	<ul style="list-style-type: none"> • Management only by the MoH • The same conditions applied to the publicly owned facilities (<i>Rede Própria</i>) and private retail pharmacies (<i>Aqui Tem Farmácia Popular</i>)
Structuring and operation	<ul style="list-style-type: none"> • Fiocruz responsible for infrastructure and management supply medicines system • MoH transfers funds to maintenance and installation of new facilities 	<ul style="list-style-type: none"> • Use of installed capacity of the private retail pharmacies in the country • Accreditation requires information technology infrastructure 	<ul style="list-style-type: none"> • Use of installed capacity of the publicly owned facilities and private retail pharmacies accredited
Medicines and health products available	<ul style="list-style-type: none"> • Reference, generics and similar (branded generics) • 112 products • Antibiotics, antiparkinsonians, antidiabetics, antihypertensives, antialergics, anxiolytics, analgesics, contraceptives, anti-inflammatories, antipsychotics, antiasthmatics, osteoporosis and condom 	<ul style="list-style-type: none"> • Reference, generics and similar (branded generics) • 41 products • Antiparkinsonians, antidiabetics, antihypertensives, antiasthmatics, dyslipidemia, contraception, osteoporosis, glaucoma and rhinitis • Geriatric diapers 	<ul style="list-style-type: none"> • Reference, generics and similar (branded generics) • 26 products • Antidiabetics, antihypertensives, antiasthmatics
Medical prescription	<ul style="list-style-type: none"> • Valid for 4 months • Contraceptives valid for 12 months • Limit of dosage monthly according clinical guidelines of the SUS • Allows the pharmacist performs interchangeability between generic and reference medicines 	<ul style="list-style-type: none"> • Valid for 4 months • Contraceptives valid for 12 months • Limit of dosage monthly according clinical guidelines of the SUS • Allows the pharmacist performs interchangeability between generic and reference medicines 	<ul style="list-style-type: none"> • Valid for 4 months • Limit of dosage monthly according clinical guidelines of the SUS • Allows the pharmacist performs interchangeability between generic and reference medicines
Price and payments to pharmacies	<ul style="list-style-type: none"> • Price of Dispensing = cost of production or procurement of the Fiocruz + administrative costs (pharmacy operating costs) • Sales collected to the Fiocruz 	<ul style="list-style-type: none"> • RP established by the MoH per pharmaceutical unit • MoH pays 90% of the RP and patient 10% to the accredited pharmacies 	<ul style="list-style-type: none"> • RP established by the MoH per pharmaceutical unit • Free of charge • MoH pays 100% of the RP to the accredited pharmacies
Control and audit	<ul style="list-style-type: none"> • Program’s Management Council (MoH and Fiocruz) • Program’s electronic authorization system (DATASUS Authorizer System) 	<ul style="list-style-type: none"> • Only MoH • Program’s electronic authorization system (“Sistema Autorizador DATASUS”) • SUS Audit Department 	<ul style="list-style-type: none"> • The same conditions applied to the publicly owned facilities (<i>Rede Própria</i>) and private retail pharmacies (<i>Aqui Tem Farmácia Popular</i>)

DATASUS — SUS Informatics Department; MoH — Ministry of Health, Fiocruz — Oswaldo Cruz Foundation; PFPPB — “Farmácia Popular do Brasil” Program; SUS — Unified Health System; RP — Reference Price.



Graph 1. Number of facilities, municipalities covered and users attended by delivery model based on accredited private retail pharmacies (*Aqui Tem Farmácia Popular*), of the “*Farmácia Popular do Brasil*” Program, between 2006 and 2012.

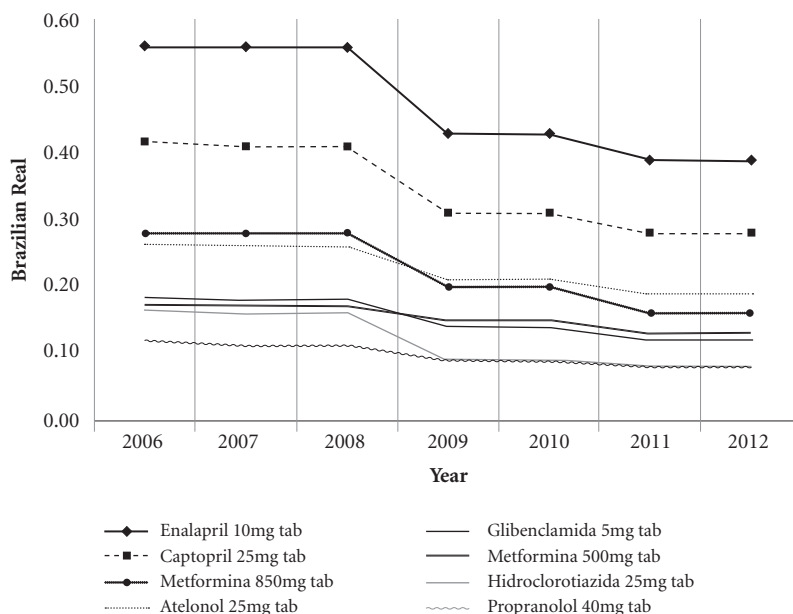
out-of-pocket purchase in private pharmacies without connection to any governmental medicines list.

The *Farmácia Popular* Program can play a role in addressing failures in public provision of medicines in the country, even if it is restricted to a specific list of medicines²². These improvements allow the population to have access to medicines. This includes non-users of the public health system (SUS) who do not have enough money to purchase and/or complete their treatment. A study in 2007, using official data showed that 46% of individuals who bought medicines in *Rede Própria* pharmacies used prescriptions from SUS⁹.

The requirement for a prescription before medicines can be dispensed from all pharmacies in the PFPB Program, even for over the counter medicines, can inhibit self-medication which is at high level in Brazil²⁶ and can help to promote rational use of medicines.

Other interesting characteristics of the PFPB are the sharing of costs with users (copayments) and the widespread use of the private retail pharmacies. In other countries, copayments have been employed to reduce costs of health care and to promote rational use of medicines²⁷. In Brazil, on the other hand, the rationale for the PFPB was always to increase access to medicines.

However, the Program is controversial, mainly because the SUS is based on the principle of free at the point of use, including for medicines available in its facilities. One of the debates is about “double taxation” as the Program is funded through general taxation and, in addition, users also need to make a contribution under the copayment scheme²⁸. Another debate is whether the PFPB is unconstitutional, on the basis that it conflicts with universal access principal of SUS as the requirement for copayment excludes those who cannot afford these payments from accessing these products¹⁰.



Graph 2. Variation of the Reference Price in the delivery model based on accredited private retail pharmacies (*Aqui Tem Farmácia Popular*), of the “*Farmácia Popular do Brasil*” Program, between 2006 and 2012.

The role of private retail pharmacies in this Program is another source of much debate. The Federal Law 10,858/2004 that created PFPB only authorized Fiocruz to sell medicines in at cost price subject to user copayment. The law did not include the private sector²⁹. It is only a Federal Decree 5,090 /2004 that applies the Law that included retail pharmacies in the private sector, generating legal uncertainty on the issue³⁰.

The expansion of a pharmaceutical service to the retail sector outside of health facilities requires State regulation of procedures for dispensing medicines³¹. The regulations are necessary because the supply of medicines outside of health facilities does not always include care and counseling, fundamental for the rational and appropriate use of medicines.

The results showed significant increase in the expansion of PFPB in both delivery models. Until 2008, this progress was mainly in the publicly owned network, after 2010 there was a

stagnation rather than expansion of facilities and municipalities covered, and a small growth in the number of users. The results show the strongest growth in the private sector (ATFP), especially after the introduction of copayment exemption for treatments of hypertension, diabetes and asthma (“Health is Priceless”).

In 2010, there was a reduction in the number of users despite the clear growth of the ATFP. This decrease may have been due to the implementation of changes in the Program, with the addition of more requirements at the point of sale, such as increasing the information in the medical prescriptions (medical number of the prescriber, date of prescription, address and user’s full name), copying and archiving prescriptions and extension of the number of documents to be filed for five years by the pharmacy. These controls were motivated by accusations of fraud disclosed in the press and increased complaints to the DAF/MoH¹⁹. On the other hand, the fol-

lowing years showed new growth, probably due to the copayment exemptions.

The geographical expansion of the PFPB is shown by the increase in pharmacies in Brazilian municipalities. In 2012, the ATFP pharmacies covered about 67% of Brazilian municipalities, in contrast, the public model, *Rede Própria*, coverage was less than 8%. However, there are differences in the geographical distribution between the two delivery models. The publicly owned network is more widespread in the Northeast and North which are the poorest regions and with limited health care services. The private model, ATFP, expanded more strongly in the Southeast and South regions, where the economy and health care systems are more developed, reflecting the characteristics of the pharmaceutical market structure in these regions^{8,22}.

The stagnation of the growth of the publicly owned network in the face of the rapid expansion of the private partnership in the Program, especially after the introduction of the copayment exemption, raises questions and suggests changes from the initial choices of the MoH of how the PFPB would be managed.

Some elements can explain this growth, for example, the large installed capacity of the private retail pharmacies in the country that facilitated the incorporation of facilities into the Program. Also, in 2010, a public financial institution, the *Caixa Econômica Federal*, which has a nationwide network of agencies, was permitted to provide the registration, membership and renewal of accreditation²².

In addition, a significant increase in the amount of the federal budget and in the spending by the MoH on the ATFP Program was identified. The payments made directly to participating pharmacies have been growing annually and already accounts for a significant share of the financing of pharmaceutical services in the SUS^{19,22}.

The geographical accessibility of PFPB was expanded by the entry of private pharmacies which help reduce barriers to access to medicines. Therefore, it is possible that the introduction of the Program improved access to medicines in Brazil, even though this also created a significant increase in the financing of the Program (which is the subject another paper in progress). The increase in the number of medicines in ATFP list (from 9 to 41 in 2012) and the copayment exemption for 24 medicines for diseases highly prevalent in the country can also facilitate access.

One study on access to medicines, using a methodology developed by World Health Orga-

nization (WHO) and Health Action International collected data for the period from 2008 to 2009 from public pharmacies, ATFP and commercial pharmacies in cities in the South of Brazil. The results showed average availability, for a set of 50 medicines, was above 90% in the ATFP Program. Overall availability ranged from 68.8% to 81.7% in the public sector³². The WHO suggests 80% as a minimum for adequate availability in primary health care, in both public and private sectors³³.

The large expansion of PFPB also highlights the centralizing role of MoH in medicines provision in Brazil. The PFPB does not change the decentralized responsibilities of states and municipalities for the provision of medicines to their populations. Moreover, it does not exempt the local managers from responsibility for the organization and management of public pharmaceutical services nor from aiming for improvements in access to and use of medicines. However, it is possible to question if one of the consequences of the expansion, especially after 2011, is that local governments neglected and transferred their responsibilities for the supply of medicines to the private sector under the ATFP Program.

There are potential uncertainties regarding the priorities of the pharmaceutical services policy of the SUS. There may be tensions between public provision of medicines and the PFPB, i.e. if the Program is complementary to the public provision or competitive^{19,24}. The lack of clarity about the relationship between these two approaches brings many challenges in ensuring the complementarity of the PFPB.

A set of ordinances published in 2006 to 2012 to regulate operational aspects of the ATFP program, affected the Reference Price of eight medicines. The average overall reduction in the RP was 33.6%, ranging from 23% (insulin isophane human) to 52% (hydrochlorothiazide 25mg).

A study performed in 2007, based on a WHO methodology adapted to the Brazilian context, collected amounts paid by users at the time of purchase and standardized prices for four drugs available in PFPB¹⁰. Different types of facilities were compared; private pharmacies, PFPB *Rede Própria* and private ATFP accredited pharmacies. The lowest prices were in the ATFP accredited pharmacies, while the non-accredited private pharmacies had the highest prices. Even though regulated, the prices of *Rede Própria* were higher than the ATFP accredited pharmacies. Hydrochlorothiazide was the cheapest product.

More recently, Bueno, Moreira and Oliveira compared prices in the PFPB with the market

prices of 15 medicines for treating cardiovascular diseases. Purchase prices were obtained from Brazil's Pharmacy Price Guide 2010, and included the Maximum Consumer Price (“*Preço Máximo ao Consumidor*”) and the 17% Brazilian state excise tax (Tax on Circulation of Goods and Services - ICMS)³⁴. The PFPB presented the lowest prices.

On the other hand, an audit report from the Brazilian Federal Government Court of Auditors (*Tribunal de Contas da União*) pointed out significant differences in the purchase prices of 13 medicines from the public sector compared to the Reference Price practiced in ATFP. The document warns that a simple tender price comparison would not be enough to distinguish if a program is more cost-effective than another because other costs involved must be considered (logistics, storage, transport and distribution)²⁴.

The study presented in this paper has some limitations. An informational bias may have occurred because the MoH, who implemented and manages the PFPB, was the main source of data. In addition, the study did not assess the impact of the different delivery models of the PFPB in

improving access to medicines, therefore, further studies should be performed.

Over the time period studied, it is clear that the expansion of the PFPB was based on the private retail pharmacies and that the MoH gave priority to this delivery model rather than the *Rede Própria*.

It should be noted that the approach to pharmaceutical services in the private model of the PFPB is based on the logic of medicine consumption as a promoter of access and on the prevailing commercial emphasis of retail pharmacies, without any emphasis on the promotion of the rational use of these products.

Finally, it is worth repeating that there are many challenges to overcome to improve the Pharmaceutical Services, which is one of the strategic pillars for the success of health care systems. These challenges are even greater because medicines are seen as products and are disassociated from a vision of access to quality health services in Brazil. Moreover, it is necessary to promote an integrated view of health, removing the vision of medicine use as a simple consumer good.

Collaborations

RM Silva participated in the design and development of the article, collection and tabulation of data, data interpretation and writing of the article. R Caetano attended the article design, data interpretation, writing and critical text revision and approval of the final version.

References

- Vieira FS, Mendes ACR. Evolução dos gastos com medicamentos: crescimento que preocupa. In: VIII Encontro da Associação Brasileira de Economia da Saúde. São Paulo: Pontifícia Universidade Católica de São Paulo; 2007. [acessado 2013 nov 22]. Disponível em: <http://abresbrasil.org.br/trabalhos/evolucao-dos-gastos-com-medicamentos-crescimento-que-preocupa.html>
- Boing AC, Bertoldi AD, Boing AF, Bastos JL, Peres KG. Acesso a medicamentos no setor público: análise de usuários do Sistema Único de Saúde no Brasil. *Cad Saude Publica* 2013; 29(4):691-701.
- Guerra Júnior AA, Acúrcio FA, Gomes CAP, Miralles M, Girardi SN, Werneck GAF, Carvalho CL. Disponibilidade de medicamentos essenciais em duas regiões de Minas Gerais, Brasil. *Rev Panam Salud Pública* 2004; 15:168-175.
- Silveira FG, Osório RG, Piola SF. Os gastos das famílias com saúde. *Cien Saude Colet* 2002; 7(4):719-731.
- Garcia LP, Magalhães LCG, Sant'Anna AC, Freitas LRS, Aurea AP. *Dimensões do acesso a medicamentos no Brasil: perfil e desigualdades dos gastos das famílias, segundo as pesquisas de orçamentos familiares 2002-2003 e 2008-2009*. Brasília: Ipea; 2013. (Texto para Discussão, n. 1839).
- Vieira FS. Gastos do Ministério da Saúde com medicamentos: tendência dos programas de 2002 a 2007. *Rev Saude Publica* 2009; 43(4):674-681.
- Vieira FS. Assistência farmacêutica no sistema público de saúde no Brasil. *Rev Panam Salud Publica* 2010; 27(2):149-156.
- Machado CV, Baptista TWF, Nogueira CO. Políticas de saúde no Brasil nos anos 2000: a agenda federal de prioridades. *Cad Saude Publica* 2011; 27(3):521-532.
- Santos-Pinto CDB, Costa NR, Osório-de-Castro CGS. Quem acessa o Programa Farmácia Popular do Brasil? Aspectos do fornecimento público de medicamentos. *Cien Saude Colet* 2011; 16(6):2963-2973.
- Pinto CD, Miranda ES, Emmerick ICM, Costa NR, Castro CGSO. Preços e disponibilidade de medicamentos no Programa Farmácia Popular do Brasil. *Rev Saude Publica* 2010; 44(4):611-619.
- Brasil. Ministério da Saúde. [acessado 2013 ago 25]. Disponível em: <http://www.saude.gov.br/medicamentos>
- Brasil. Ministério da Saúde. [acessado 2013 jun 19]. Disponível em: <http://www.saude.gov.br/saudelegis>
- Brasil. Ministério da Saúde. [acessado 2013 ago 25]. Disponível em: <http://bvs.saude.gov.br/>
- Fundação Oswaldo Cruz. Relatório Anual de Gestão 2011. [acessado 2012 maio 22]. Disponível em: http://portal.fiocruz.br/sites/portal.fiocruz.br/files/documentos/Relatorio_gestao_2011.pdf
- Fundação Oswaldo Cruz. Relatório Anual de Gestão 2011. [acessado 2013 jun 13]. Disponível em: [https://portal.fiocruz.br/sites/portal.fiocruz.br/files/documentos/RG_fiocruz_2012_v01%20\(2\).pdf](https://portal.fiocruz.br/sites/portal.fiocruz.br/files/documentos/RG_fiocruz_2012_v01%20(2).pdf)
- Ministério da Saúde. 2013. Sala de apoio à gestão estratégica. 2013. [acessado 2014 jan 3]. Disponível em: <http://www.saude.gov.br/sage/>
- Brasil. Lei nº 12.527, de 18 de novembro de 2011. Regula o acesso a informações previsto no inciso XXXIII do art. 5º, no inciso II do § 3º do art. 37 e no § 2º do art. 216 da Constituição Federal; altera a Lei nº 8.112, de 11 de dezembro de 1990; revoga a Lei nº 11.111, de 5 de maio de 2005, e dispositivos da Lei nº 8.159, de 8 de janeiro de 1991; e dá outras providências. *Diário Oficial da União* 2011; 18 nov.
- Junges F. *Avaliação do Programa Farmácia Popular do Brasil: aspectos referentes a estrutura e a processos* [dissertação]. Porto Alegre: Universidade Federal do Rio Grande do Sul; 2009.
- Pereira MA. *Programa Farmácia Popular no Brasil: uma análise sobre sua relação com o Complexo Econômico-Industrial da Saúde e os programas estratégicos do Governo Federal* [dissertação]. Rio de Janeiro: Escola Nacional de Saúde Pública Sérgio Arouca; 2013.
- Brasil. Ministério da Saúde. Portaria nº. 971, de 15 de maio de 2012. Dispõe sobre o Programa Farmácia Popular do Brasil. *Diário Oficial da União* 2012; 17 maio.
- Brasil. Ministério da Saúde. Manual Básico Rede Própria. [acessado 2012 ago 15]. Disponível em: <http://bvs.saude.gov.br/>
- Silva RM. *Programa "Aqui tem Farmácia Popular": expansão entre 2006-2012 e comparação com os custos da assistência farmacêutica na Secretaria Municipal de Saúde do Rio de Janeiro* [tese]. Rio de Janeiro: Universidade do Estado do Rio de Janeiro; 2014.
- Brasil. Ministério da Saúde. Manual de orientações às farmácias e drogarias credenciadas no "Aqui Tem Farmácia Popular". Brasília. 2014. [acessado 2014 jun 13]. Disponível em: <http://portalsaude.saude.gov.br/images/pdf/2014/abril/23/MANUAL-aquitem.pdf>
- Brasil. Tribunal de Contas da União (TCU). *Relatório de auditoria operacional: Farmácia Popular*. Brasília: TCU, Secretaria de Fiscalização e Avaliação de Programas de Governo; 2011.
- Brasil. Ministério da Saúde. Portaria nº 491, de 09 de março de 2006. Dispõe sobre a expansão do Programa "Farmácia Popular do Brasil". *Diário Oficial da União* 2006; 10 mar.
- Schmid B, Bernal R, Silva NN. Automedicação em adultos de baixa renda no município de São Paulo. *Rev Saude Publica* 2010; 44(6):1039-1045.
- Austvoll-Dahlgren A, Aaserud M, Vist G, Ramsay C, Oxman AD, Sturm H, Kösters JP, Vernby A. Pharmaceutical policies: effects of cap and co-payment on rational drug use. *Cochrane Database Syst Rev* 2008; (1):CD007017.
- Aragão Júnior GA. *Avaliação política do programa Farmácia Popular do Brasil à luz dos princípios do Sistema Único de Saúde* [dissertação]. São Luís: Universidade Federal do Maranhão; 2012.
- Brasil. Presidência da República. Lei nº 10.858, de 13 de abril de 2004. Autoriza a Fundação Oswaldo Cruz - Fiocruz a disponibilizar medicamentos, mediante ressarcimento, e dá outras providências. *Diário Oficial da União* 2004; 14 abr.

30. Brasil. Tribunal de Contas da União (TCU). *Representação sobre a expansão do Programa Farmácia Popular do Brasil – Sistema de Copagamento para a rede privada de farmácias sem aprovação de lei específica*. Brasília: TCU, Secretaria de Fiscalização e Avaliação de Programas de Governo; 2010.
31. Menicucci TMG. A reforma sanitária brasileira e as relações entre o público e o privado. In: Santos NR, Amarante PDC, organizadores. *Gestão pública e relação público privado na saúde*. Rio de Janeiro: CEBES; 2011. p. 180-197. (Coleção Pensar em saúde).
32. Bertoldi AD, Helfer AP, Camargo AL, Tavares NU, Kanavos P. Is the Brazilian pharmaceutical policy ensuring population access to essential medicines? *Globalization and Health* 2012; 8:6.
33. World Health Organization (WHO). *WHO Medicines Strategy 2008-2013* [draft]. Geneva: WHO; 2008.
34. Bueno CS, Moreira AC, Oliveira KR. Preço dos medicamentos utilizados nas doenças cardiovasculares no Brasil. *Rev Panam Salud Publica* 2012; 31(1):62-67.

Article submitted 15/07/2014

Approved 28/01/2015

Final version submitted 30/01/2015