

**Decentralisation of pharmaceutical assistance  
in Brazil: impacts on access to medicines**

**A thesis submitted for the degree of Doctor of Philosophy**

**by**

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**September 2013**



## ACKNOWLEDGEMENTS

I would like to thank the Camara Legislativa do Distrito Federal for providing me with the sabbatical leave that made it possible for me to complete my PhD at Brunel University. I am especially indebted to my colleagues in the *Assessoria Legislativa*, and particularly those in the *Unidade de Saúde, Educação, Cultura e Desenvolvimento Científico e Tecnológico*, who have been tremendously supportive, encouraging and helpful throughout this period of studies.

I am truly grateful to all my interviewees and informants for their time and co-operation; the ideas they shared with me; and the many insights they have allowed me to draw.

My heartfelt thanks go to my supervisor, Dr Barbara Prainsack, for the encouragement, guidance, patience and support she has provided me with over this period of studies. I feel truly fortunate to have had her as my supervisor. I will never forget the help and support Dr Jason Hughes gave me in the search for a new supervisor in 2012. I would also like to thank Dr Timothy Millewa for his guidance and supervision in the first stage of my work and Professor Christina Victor for her help at decisive moments in my time at Brunel.

I am grateful to the whole of the Department of Sociology and Communications for providing me with the necessary support and help. I would particularly like to thank Amreen Malik and Ushma Gudka, who have been immensely supportive in many ways.

My beloved parents and brothers, who have supported and encouraged me unconditionally in every aspect of my life, inspired and drove me on towards my objective. My deepest love and gratitude go to my husband Claudio, and my children Flavio and Gabriela, who have always been at my side providing patient support and restoring my spirits with laughter and tenderness. Their love has given me the motivation to complete this work. My husband Claudio was also a great office-mate during the long writing hours we shared in our tiny study in London. In addition to my family I owe many thanks to my friends in London and Brazil for their support, help and friendship.

## ABSTRACT

This thesis explores how decentralisation of basic pharmaceutical assistance was introduced in Brazil. Decentralisation aimed to improve access to basic medicines. Nevertheless, the inconsistency in the availability of medicines in the Brazilian public health system (SUS - Unified Health System) justified the development of two seemingly contradictory, yet co-existing, approaches: decentralisation and recentralisation.

The central question of my thesis was how the simultaneous processes of decentralisation and recentralisation, which took place between 1998 and 2011, have affected access to medicines distributed by SUS. My second aim was to explore how political and power dynamics impacted the implementation of decentralisation policies. I carried out semi-structured interviews with key actors in policy-making for pharmaceutical assistance; interviewees were selected from among the health secretaries and Ministry of Health officials that participated in interfederative boards of agreement. The Grounded Theory approach, as well as documentary analysis, informed my data collection and analysis.

My findings suggest that decentralisation was important for improving the availability of medicines, although levels of improvement varied across the country. Decentralisation in itself was not sufficient to improve the availability of medicines largely due to the regional differences. Federative relationships involved in the decentralised management of pharmaceutical assistance are seen as important by health secretaries, but are considered laborious and time-consuming by Ministry of Health officials. Lack of compliance with agreements at state level was mentioned as one of the main barriers to further improving access to medicines. In this context of struggle, the Popular Pharmacy programme, controlled by the federal government, was created in 2004. The initiative, which can be regarded as a recentralisation process, rapidly improved the availability of basic medicines. There is no clear indication of which is the best approach for improving access to basic medicines in Brazil. Both decentralisation and centralisation worked well in some contexts but failed in others.

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# CHAPTER ONE

## INTRODUCTION

### 1.1 Introduction

Access to essential medicines in developing countries is part of the Millennium Development Goals (MDG). It is considered a fundamental part of adequate health care, and is one of the explicit targets of the eight international development goals established in 2000 by the United Nations. They are to be achieved by the year of 2015.<sup>1</sup> The World Health Organization (WHO) regards the “equitable availability and affordability of essential drugs as a key indicator for health care quality and their availability is a pre-requisite to provide effective care” (WHO, 2002a). Concurrently, health system reforms in recent decades have often been premised upon the need to decentralise the management, funding and delivery of health services. A plethora of studies have argued the case for decentralisation as a means to support and develop health services that will better match the needs and preferences of citizens (Willis and Khan, 2009; Koranteng and Larbi, 2008; Bossert, Larrañaga and Ruiz Meir, 2000; De Vries, 2000). This pro-decentralisation move also reached the Brazilian health system.

Brazil moved towards decentralisation as part of the re-democratisation process that started in the 1980's.<sup>2</sup> The health sector was the first to be decentralised after some initiatives to promote political and fiscal decentralisation (Falleti, 2010:153). The turning point of the health sector in Brazil was the establishment of the Unified Health System (SUS - Sistema Único de Saúde) by the Constitution of 1988, which accentuated the country's re-democratisation. Decentralisation is one of the pillars of the health system reform that distributed power and responsibilities to subnational levels. In essence, after the 1988 Constitution was enacted and SUS created, municipalities became responsible for health care provision, whereas states were expected to provide technical and

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<sup>1</sup> To provide access to affordable essential medicines in developing countries is within the targets of the 8<sup>th</sup> goal. The goals are: 1) Eradicating extreme poverty and hunger; 2) Achieving universal primary education; 3) Promoting gender equality and empowering women; 4) Reducing child mortality rates; 5) Improving maternal health; 6) Combating HIV/AIDS, malaria, and other diseases; 7) Ensuring environmental sustainability, and; 8) Developing a global partnership for development. Source: United Nations, available at <http://www.un.org/millenniumgoals/global.shtml> [last accessed 06/08/2013].

<sup>2</sup> From 1964 to 1985 Brazil was under military rule.

financial support. Lastly, the federal level controls the budget, and decides on national policies and priorities.<sup>3</sup>

Following the decentralisation of the health care system, basic pharmaceutical assistance also went through a process of decentralisation from 1998 onwards. Pharmaceutical assistance is a term created in Brazil to designate health care activities involving pharmaceutical drugs (Marin *et al.*, 2003).<sup>4</sup> In this sense, the public delivery of medicines by SUS and its management is also part of pharmaceutical assistance.<sup>5</sup> The main justifications for decentralising the provision of medicines were the then insufficient access to essential drugs and the need for a more effective use of local knowledge and resources to address local needs. According to the WHO definition, essential drugs or “essential medicines are those that satisfy the priority health care needs of the population” (WHO, 2002b).<sup>6</sup> Medicines for the treatment of diabetes and hypertension are examples of essential medicines. According to WHO guidelines, these drugs should be available in health systems continuously, in sufficient amounts and appropriate dosages to meet the needs with assured quality and affordable prices.

Although the decentralisation of the responsibilities and management for the provision of basic medicines has been implemented across the country for some time already, it has not produced the expected impact in terms of improved access. In fact, there are some data on coverage of free provision of essential drugs (which I will discuss in the literature review, in Chapter Two) suggesting that the issue of access to medicines has not been solved. A fact that does support this hypothesis is the increasing number of court cases brought by users against SUS in attempts to obtain drugs, mainly high-cost medicines, but also for medicines of primary care which, in theory should always be available in public pharmacies (Marques and Dallari, 2007; Vieira and Zucchi, 2007; Messender, Osorio-de-Castro and Luiza, 2005). These widespread court cases, which led to

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<sup>3</sup> Brazil is a federation arranged in 27 states and 5570 municipalities. The three levels are autonomous and guided by the national constitution.

<sup>4</sup> This work uses pharmaceutical drugs, drugs, medicines, medications and medicaments as synonyms.

<sup>5</sup> Pharmaceutical assistance includes provision of all classes of medicines from those used for the most prevalent diseases to those involved in complex treatments such as cancer. This thesis is limited to basic pharmaceutical assistance, i.e. the activities involved in the provision of medicines used in primary care.

<sup>6</sup> Essential medicines include not only drugs intended for primary care but can also include some medicines involved in treatments in secondary (medical specialists) and tertiary care (hospitals). In this work, however, essential medicines are limited to those used in primary care. Essential drugs, basic medicines, primary care drugs, and primary care medicines are used in this thesis as synonyms to designate the drugs used in primary care services.

the term 'judicialisation' being coined, have contributed to the worsening of the public provision of medicines as significant resources are tied up in providing drugs to a limited number of patients.

Another challenge to the adequacy of the decentralised model of drug provision came from the federal government. In what can be regarded as a move towards recentralisation, the Ministry of Health has been allocating considerable financial resources to a centralised programme for the distribution of basic medicines. In 2004, the Federal Government launched the Popular Pharmacy Programme, which emerged as an important initiative towards the expansion of access to medicines. The programme is an innovative federal policy that established a users' co-payment scheme for the purchase of medicines in public and community pharmacies.<sup>7</sup> It operates independently from and in parallel with the public distribution of medicines provided by the municipalities. According to the Ministry of Health it was introduced as a strategy for complementary access to drugs (Ministerio da Saude, 2005b). This programme expanded over the years, and is now widespread across the country. Since 2011, the Popular Pharmacy programme has also been distributing medicines to treat diabetes and hypertension, free of charge. Subnational actors<sup>8</sup> did not participate in this initiative, which is managed and funded by the federal level. The way this programme entered the policy agenda and was implemented shows particular features that clearly suggest a change in the federative relations that command the basic pharmaceutical assistance policies.

Another intriguing characteristic within the complex context of public pharmaceutical assistance in Brazil is the federal programme to fight STD/AIDS, which has brought remarkable advances in terms of access to medicines. This programme, considered an international model by many researchers, provides free medicines for all who need them. It has a special configuration that had not been used in the design and implementation of other initiatives within the pharmaceutical assistance in the country. The funding and purchasing are centralised and, in 2008, the expenses of the Ministry of Health with the purchase of antiretroviral drugs (ARV) to treat around 180,000 patients, was about US\$ 0.4 billion. That amount represented approximately 20% of total expenditure on medicines by the federal level in that year (Barbano, 2008). The resources invested to treat this relatively small group of patients (considering the total population of Brazil as being close to 197m), contrasts with the resources used to provide the whole list of basic medicines to

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<sup>7</sup> Public pharmacies refer to SUS pharmacies, whereas community pharmacies are private businesses.

<sup>8</sup> In my work the terms 'subnational actors' or 'subnational level' refer to state and municipal levels of government, in this case state and municipal health secretariats.

primary care services. In 2007 the Ministry of Health spent US\$179 million on basic medicines while US\$400 million were spent to purchase ARV drugs (Vieira, 2009). One could argue that the individual cost of ARV medications is high, and this may explain why it necessitates such a large amount of money. Despite basic medicines being cheaper than ARV drugs, there are a large number of patients to be treated and low availability in the public sector indicates that the demand for basic medicines is not being met. In this context, the decision to invest more money in STD/AIDS than in basic medicines is in line with an explicit government priority.<sup>9</sup> Comparing public delivery of essential medicines and the federal STD/AIDS programme, the differences in terms of access and coverage are remarkable. The STD/AIDS programme has succeeded in distributing ARVs, funded and purchased by the Ministry of Health, for all patients in need, whereas provision of essential medicines has not reached sufficient coverage.

These different approaches to medicine provision could indicate that pharmaceutical assistance is still being developed and the content of the particular policy depends on the nature of the disease to be treated and the context in which the policy emerged. This thesis explores the relationship between decentralisation, recentralisation, and access to medicines in Brazil. Before introducing my central research problem and research questions, it is necessary to provide the context of my research, as well as the key themes guiding my investigation.

This chapter is divided into seven sections. The second section explores the context within which health system reform occurred in Brazil. The third discusses the decentralisation of the health sector. The fourth section gives an overview of the Brazilian health system and the interplay between the public and the private subsystems. The fifth section discusses the development of pharmaceutical assistance within SUS, and the two subsequent sections explain the research problems and the structure of the thesis, respectively.

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<sup>9</sup> The reasons for the distribution of ARV drugs having received significant attention and funds appear to be linked to the acute nature and the high degree of mortality of the disease. AIDS received much international attention and funding in the 1990s. The STD Department founded in 1986 was responsible for the management of these funds, the treatment guidelines, and the ARV purchase and distribution in the country. This strategy of centralised administration achieved many positive results, which in turn accredited the department for receiving increasing investments.

## 1.2 Background to health system reform in Brazil

The impetus for reforming the Brazilian health care system arose during a protracted period of military rule between 1964 and 1985. This period was marked by a political focus upon economic development at the expense of social welfare policies and a conscious inculcation of the private health sector – trends that helped to accentuate inequalities in access to health care and medicines (Labra, 2001; Horn, 1985). Public health programmes were limited to immunisation campaigns and epidemic controls overseen by the Ministry of Health (Souza, 2002a). At the same time, in terms of health care, the National Institute of Medical Assistance and Social Care (INAMPS – *Instituto Nacional de Assistencia e Previdencia Social*) was responsible for medical and hospital service provision under the direction of the Ministry of Social Security. Yet INAMPS was a centralised, contribution-based system restricted to workers in the formal job market (Lobato and Burlandy, 2000). Those covered by this contributory system were concentrated mainly in urban centres in the south and southeast regions of Brazil. Consequently, large hospitals and private sector contractors in the health field were concentrated in these more developed and populated areas (Souza, 2002b).

Indeed, state expenditure on health care was proportional to the total funds raised by contributions within each region. This matched national demand with health care provision but exacerbated geographical and social inequalities.<sup>10</sup> People excluded from such provision could purchase private health care if they had the resources for it; if not, they had to rely on philanthropic hospitals and institutions. Even though the differences between regions have been decreasing over time, geographical and social inequalities in morbidity and mortality rates are still important in Brazil. For instance, in 2006, the infant mortality rate in the northeastern region was two times higher than that of the southern region (Victora *et al.*, 2011).

The *sanitarista* movement (a pro-public health movement) emerged in the mid-1970s within the context of wider calls for re-democratisation of the country and was dedicated to a democratic reform of the health sector. The *sanitarista* movement was a loosely organised coalition of social and political groups which included progressive health care professionals, scholars, trade unionists and popular social movements, and it forged broad links with opposition political parties. The movement, largely composed of and headed by health care professionals, aimed to tackle what was seen as an unequal and inefficient system of health care that focused on cure at the expense of

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<sup>10</sup> In general, the southeast region is more economically developed whereas the north and northeast regions are less developed.

prevention. The extent to which the movement reflected wider societal support is still a subject of considerable debate (Cohn, 2008; Weyland, 1995; Ministerio da Saude, 1986). The *sanitarista* movement, which had a clear reform proposal, had defined the strategy of gaining access to positions within public institutions in the health sector in order to support the reforms (Dowbor, 2007). Despite ideological differences with the military regime which ruled the country, the movement's health professionals worked in state institutions at all three federative levels. The movement's state-centred strategy meant that, when the return democracy took place, many *sanitarista* activists would already be in position to become policy makers in order to secure the desired reforms.

The health reforms which sought to place the state at the centre of public service delivery took place in an unfavourable political and historical context, however. Neo-liberal thought was underpinning health system reforms in some other Latin American countries; and there was a more general re-evaluation of state-centred welfare (Campos, 2007). The privatisation of public sector provision was evident in many countries. In this scenario, the foundation of SUS and its incorporation into Brazil's Constitution in 1988 appear quite radical. Access to health care was framed as a constitutional right - a "duty of the state" and a "right of the citizen" (Brasil, 1988). The founding principles of SUS, thus, encompass universal access, equity and comprehensive care. Decentralisation, in this context, was believed to be a way of improving public health in Brazil, as I will discuss in the next section.

### **1.3 Health reforms within the context of decentralisation in Brazil**

From the 1980s onwards Brazil implemented decentralisation policies that, along with constitutional and electoral reforms, aimed to transfer some responsibilities, resources and authority from higher to lower tiers of government (Falleti, 2010:150). Political decentralisation included the return to elected governors (between 1980 and 1982) and the recognition of municipal autonomy by the Constitution of 1988. The partial decentralisation of fiscal resources, increasing automatic transfers of revenues to states and municipalities, started in 1980 and was reinforced in 1988 with the enactment of the Constitution. The last type of decentralisation policy implemented was administrative, and the first changes arising from this occurred in the health sector. Unlike other developing countries that embraced decentralisation of central government functions in the

1980s but granted few revenue-raising power to local levels (Mills *et al.*, 1990), Brazil's decentralisation of health services was preceded by partial fiscal decentralisation (Falleti, 2010:151).

Before considering the reforms in detail it is useful to recall the political and economic environment within which the new policies were introduced. In overall terms, the health reform agenda in the 1990s often ran counter to the orthodoxies of political and economic reforms entrenched in the 1980s (in particular, the "opening" of the economy championed by neo-liberals) (Atkinson, 2002; Costa, 2002). Impediments to change included the remarkable scale of social and economic inequality in Brazil, the characteristics of Brazilian federalism and the impact of continuing arguments in favour of privatisation in the health sector (Levcovitz, Lima and Machado, 2001). Neo-liberal reforms that began in the 1980s had stressed the need for structural adjustment in the economy, and in times of high inflation, an emphasis was placed on measures to stabilise the currency. The reforms also encompassed privatisation of state enterprises, the adoption of institutional reforms to reduce the size of the state and the introduction of a new framework for a more professional civil service, which required a public examination for civil servants to join the career. Although decentralisation was the only principle of SUS that did not conflict directly with these precepts in the 1990s, there was still tension in its creation.

The *sanitarista* movement advocated decentralisation in order to bring health services closer to citizens' needs, to expand democratic space, social participation and the role of local governments (Campos, 2006). On the agenda of Brazilian health reforms, decentralisation has always been linked to broader issues such as the strategy of democratisation and incorporation of new social actors (popular or social participation) (Levcovitz, Lima and Machado, 2001). Nevertheless, the neo-liberal project of state reform advocated decentralisation as a strategy for modernising public administration and reducing the state's role in order to minimise the costs generated by the idea of universal health care.

At this point is important to remark that the most prominent example of broad participation of various social sectors in policy-making process was the Eighth National Health Conference, held in 1986, which promoted a wide-ranging discussion of SUS project proposed by the *sanitarista* movement. This Conference drafted SUS, which was made a reality subsequently to the

promulgation of the Constitution of 1988 (Fleury, 1997). The National Conferences and National Health Council are formal instances of participation and agreement (Guizardi *et al.*, 2004).<sup>11</sup> These are spaces where civil society is given the opportunity to participate in assessing and setting guidelines for health policies. The Health Council has the function of controlling and monitoring the implementation of policy, while the Health Conferences represent a public arena for democratic deliberation about guidelines and assumptions that should inform health policy-making in Brazil.

As a result of this movement, the 1988 Federal Constitution, known as the *Citizens' Constitution*, included health as a social right (Brasil, 1988). According to this constitutional principle, the state must provide the necessary conditions for the effective functioning of the health model proposed. Access to health care was, after all, a right of every Brazilian citizen. These principles were implemented in the creation of SUS, making the state responsible for maintaining a decentralised, universal and equitable health system. In 1991, the Health Organic act, in consonance with SUS's constitutional principles of universality and comprehensiveness, included free access to medicines amongst the health rights.

The decentralisation of the health system was a *sine qua non* for the accomplishment of the newly created SUS, and the reforms proposed demanded the development of complementary legislation. New regulations, rules, and administrative reforms were needed at all levels of government.

Turning to the drive for decentralisation, from 1991 a series of operational directives from the Ministry of Health attempted, gradually, to transfer responsibilities for health services to the municipal level. The Basic Operational Standards (NOB), a type of ministerial order, was fundamental to the detailed division of responsibilities between the three levels of government.<sup>12</sup> The relationship between health stakeholders and the criteria and mechanisms for granting federal funds to subnational levels of government were the initial focus of these instruments. Within these norms, those related to funding and payment were of particular importance in the decentralisation process. Although the norms were introduced to implement decentralisation, it has, parenthetically,

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<sup>11</sup> The hierarchy of those instances of agreement within SUS structure is summarised in Figure 1.1.

<sup>12</sup> NOB means 'Basic Operational Norm' and NOAS are 'Health Assistance Operational Norms'. Four regulatory norms setting the operational standards were issued between 1991 and 2001 - NOB 91, NOB 93, NOB 96 and NOAS 2001.

been argued that the NOBs were simultaneously a tool to strengthen the regulatory powers of the Ministry of Health (Levcovitz, Lima and Machado, 2001).

Regarding funding, from its inception until 1998, SUS has worked through a complex and centralised payments system by which providers, both public and private, have received moneys on the basis of service provision. This payment system meant that the federal level made monthly payments according to the bills sent in by public (state or municipally owned) and private providers (Collins, Araujo and Barbosa, 2000). From this perspective, the central government's goal was to control the health policy through federal administrative actions based on 'authorized budget' transfers that would not leave much scope for autonomy on the part of local governments (Trevisan, 2007). Similarly, there are claims that municipal autonomy is restricted because the transfer of funds is tied to specific actions and assistance programmes and that the federal government has used transfers to make wealthy states even wealthier (McCullaugh, 2009). Analysing the extensive use of orders at the federal level, Baptista (2007) argues that the Ministry of Health has adopted a centralising approach – financial and administrative tools make state and municipal governments subject to the system's rules – without creating a more democratic and negotiated approach to the formulation of health policy.

The complexity of SUS required incremental changes to implement mechanisms that would overcome potential conflicts and contradictions inherent to the distribution of responsibilities at subnational levels (Goulart, 2001). Thus, the decision-making structures of government were expanded to include social participation<sup>13</sup> and to promote the building of alliances between stakeholders in order to incorporate the requirements brought by the decentralisation process. Key changes included the creation of Health Councils and Tripartite and Bipartite Intergovernmental Commissions (CIB and CIT, respectively) – bodies that would include representatives of the National Councils of State and Municipal Health Secretaries (CONASS and CONASEMS, respectively) in addition to the Ministry of Health representatives. In 1993 the government not only deepened the municipalisation process, but also implemented the interfederative boards of negotiations (Tripartite Intergovernmental Commission – CIT and Bipartite Intergovernmental Commissions – CIBs) in a favourable political environment resulting from the change in President of the Republic (Ministerio da Saude, 1993).

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<sup>13</sup> Institutionalized popular participation is provided by the Health Councils and Health Conferences at the three levels.

The new federal health officials were clearly identified with the *sanitarista* movement, being more receptive to the proposed increase in municipalisation and decentralisation of the system. The institutional design planning and management of SUS remains in effect until today, featuring permanent forums of vertical and horizontal coordination. These bodies were cast as central to building relationships between stakeholders at federal, regional and municipal levels. These institutionalised forums introduced innovative features to Brazilian governance, enabling a greater number and variety of stakeholders to participate in the decision-making process. A clearer definition of each government level's responsibilities in implementing health policy was also achieved (Miranda, 2007).

Secondly, another change introduced as the implementation of decentralisation progressed was the automatic transfer of federal funds (on either fixed or variable *per capita* basis) to replace the payment for service provided. The automatic transfer of financial resources from federal to municipal funds created a direct relationship between the federal and municipal levels. These transfers were linked to greater autonomy for the municipal manager and the decentralisation of health resources to thousands of municipalities which, until then, had not received federal funds directly (Goulart, 2001; Levcovitz, Lima and Machado, 2001). In 1996, the NOB-96 detailed the conditions under which municipalities would assume responsibility for the health needs of their populations (Andrade, Pontes and Martins Junior, 2000). In order to acquire authority over local health services, municipalities had to undergo a process of accreditation against pre-determined criteria. Data provided by the Ministry of Health indicate that most of the progress towards decentralisation took place in 1998, but there was some variation as to what extent municipalisation was adopted and, even now, the process is still not complete (Aguiar, 2006).

It was, however, in the field of primary health care that the changes resulting from the implementation of SUS were most evident (Aguiar, 2006). Three major primary health care programmes were implemented in the 1990s: the Primary Care Quota (PAB – *Piso da Atenção Básica*), the Community Health Agents Programme (PACS – *Programa de Agentes Comunitários de Saúde*) and the Family Health Programme (PSF – *Programa Saúde da Família*). Additionally, a coordination mechanism called the 'Primary Care Pact' (*Pacto de Indicadores da Atenção Básica*) was used to assess the progress of municipalities.

The Primary Care Quota introduced in 1998 is a per capita-based federal transfer to fund primary care services provided at the local level. It is assigned according to a formula based on resident population within each municipality. To receive these transfers, municipalities were required to engage in a process of voluntary accreditation. Municipal governments could apply for full management of basic care (primary care services only) or full management of the entire health system in the municipalities. The requirements for accreditation in full management of basic care include: the creation of a municipal health council (to provide popular participation) and a municipal health fund (to receive the moneys); the design of the municipal health plan, and the provision of evidence of technical, managerial and administrative capacity (Ministerio da Saude, 1997).

Nevertheless, even today the remit of municipalities is not standardised across the country. Currently there are three situations regarding the management of health in municipalities: 82% have joined the management pacts, 17% did not join the pact and hold only management of primary health care; and about 1% is accredited to the full management of the health system within the municipality.<sup>14</sup>

The Community Health Agents Programme, introduced in 1991, involved the employment of local workers under the supervision and management of a nurse.<sup>15</sup> The programme used the existing local infrastructure of clinics to provide working space for the nurses and community health agents, but a large proportion of the work of the agents entails home visits (Ministerio da Saude, 1997). By 1997, 30 million people were being served by the programme (Svitone *et al.*, 2000). In 1997, the Ministry of Health merged the Community Health Agents programme into a broader programme – the Family Health Programme. Community Health Agents have remained central to service delivery, but the scheme has incorporated other health professionals, including general practitioners, nurses and nursing assistants. In some areas, dentists, dental hygienists, dental assistants and social workers have been included as well (Escorel *et al.*, 2007). Each team works within a geographic jurisdiction and is responsible for monitoring the health status of the population living in that area, providing primary care services and making referrals to other levels

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<sup>14</sup> Source: Sage website from the Ministry of Health <http://189.28.128.178/sage/>, accessed in 25/05/2013.

<sup>15</sup> Each nurse oversees a maximum of 30 agents and each community health agent is assigned to a specific geographical area, providing service for up to 150 families or 750 individuals.

of care as required.<sup>16</sup> The programme encompassed 96% of Brazilian municipalities by 2007, representing 50.7% of the population (about 96 million inhabitants) (Ministerio da Saude, 2009b). The initiative has already been linked to a reduced infant mortality rate in Brazil (Macinko, Guanais and Souza, 2006).

More broadly, the Family Health Programme combines both centralised and decentralised features (Aguiar, 2006). On the one hand, municipalities can decide on many aspects of management but, on the other hand, they are subject to federal guidelines specifying the composition of the health teams, the number of people that each team is intended to serve, the responsibilities of each health care professional and the main health conditions that the programme is supposed to target. The rationale for such control is maintenance of national policy objectives and standards, and to avoid the potential capture of local systems by municipal agents for their own political gain.

Advancing the decentralisation policy arrangements, in 1999 the federal government introduced the Pact of Indicators of Primary Care as a coordination mechanism. The process, led by the Ministry of Health, in partnership with state and municipal health secretariats, incorporated mechanisms for the monitoring and evaluation of health services based upon targets to be agreed between the three levels of SUS management (Ministerio da Saude, 2000a).<sup>17</sup> Under the pact, the three levels of government negotiate annual targets, based on health indicators, for each municipality. Based on the fulfilment of those targets, the federal government accredits states and municipalities for the autonomous management of health services (Ministerio da Saude, 2003). The transfer of federal health funds for primary care could, in theory, be withheld if municipalities failed to regularly supply data on primary care indicators, or if they failed to establish mechanisms for popular participation in the municipal health council. Penalisation for non-compliance is often difficult or complicated to enforce, though. Penalisation would normally entail the withholding of federal funds, which could affect municipal health services in undesirable ways and undermine the rationale for health pacts in the first place.

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<sup>16</sup> Each team should be responsible for between 600 and 1000 families (2400-4500 people).

<sup>17</sup> These targets include, for instance, decreasing the incidence of malaria in the Amazon region to less than 30% and improving the quality of care to the elderly living in institutions for long periods.

This trend of signing agreements on targets has been on the rise since 2006 when some of these rules and regulations were replaced by less hierarchical arrangements - the Pact for Health, an agreement in which managers at every level of government are committed to complying with health objectives and responsibilities (Ministerio da Saude, 2006). The Pact for Health approved by the CIT in January 2006 brought innovation to the process of entitlement for states and municipalities. The Pact aimed to establish joint responsibility in SUS more clearly, in which all managers are considered to be invested with full responsibilities, replacing the former accreditation process with a new system where they should observe the Statement of Commitment and Management (TCG). The TCG has the goals and objectives of the Pact for Health, the duties and responsibilities of each manager and the corresponding monitoring indicators. Another important element introduced by the Pact concerned the financial resources that changed from monthly payments linked to the service delivered, to 'block funding' corresponding to a certain amount of money to finance the services required to reach the targets agreed in the TCG. Financial incentives for the development of management and planning capabilities were also provided under this new paradigm of funding.

Despite criticism related to the delays in care, long queues and shortage of drugs, opinion surveys on health have been showing a steady rise in the population's satisfaction with the available services on the public health system. In 2010, the survey of the System of Indicators of Social Perception (SIPS) conducted by the think-tank Institute of Applied Economic Research (IPEA – *Instituto de Pesquisa Econômica Aplicada*) indicated that the services best evaluated by the population that uses SUS were the visits by the teams from the Family Health Programme (80.7% of respondents) followed by the distribution of free drugs (69.6%) (IPEA, 2011). Alternatively, according to IPEA, the most common problems mentioned were lack of doctors (58%), delay in treatment in the Basic Health Units (UBS – *Unidades Básicas de Saúde*) and hospitals (35%) and delay for consultation with medical specialist (33.8%). Taking these data into consideration, it would be reasonable to conclude that although decentralisation is still underway, improvements in health care, if any, are slow and it is difficult to assess their efficacy.

At this point, after this brief discussion on how the public health system developed, it is vital to have a general overview of how the whole Brazilian health system is configured. In the next section, drawing on the work of Paim *et al.* (2011) and others, I will outline how SUS currently works and how it interacts with the private sector.

## **1.4 The Brazilian health system**

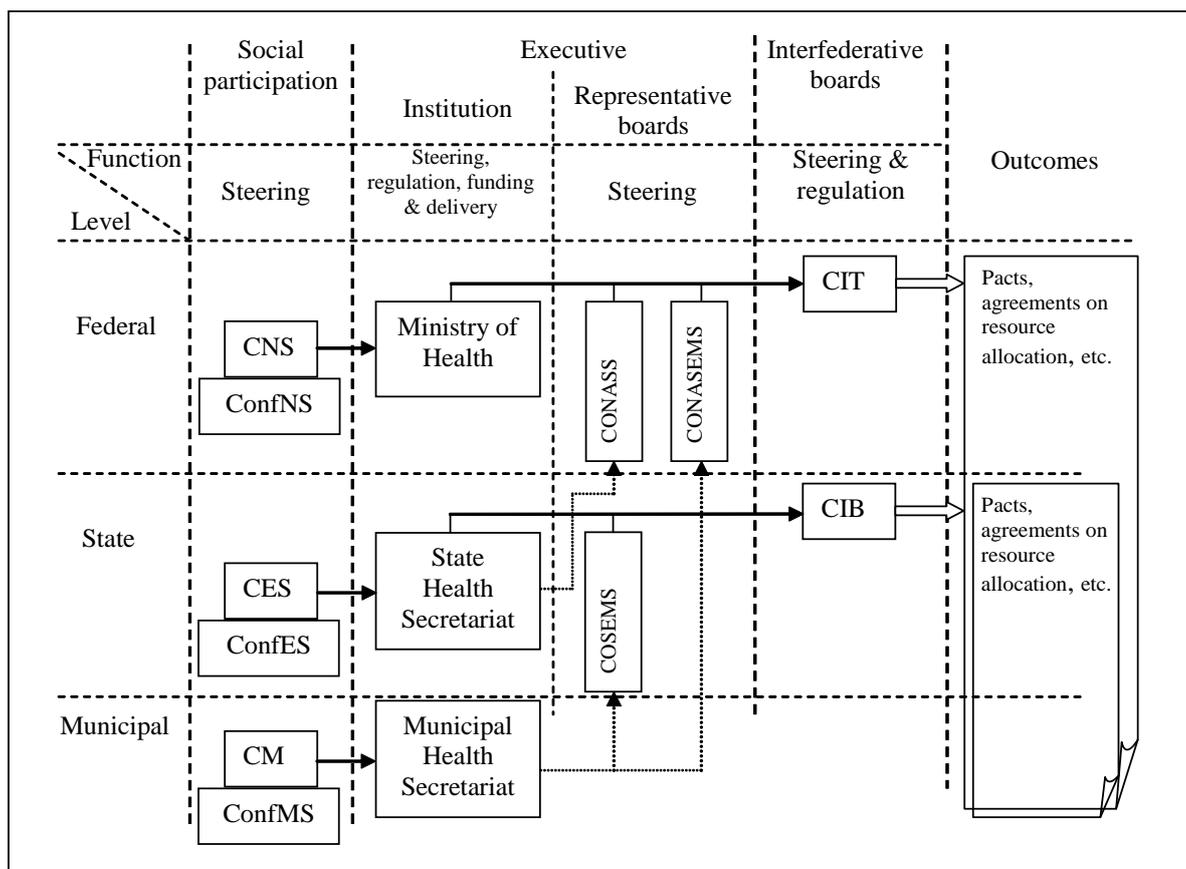
The health system in Brazil developed as a complex network of public and private components with participation of complementary and/or competitive service providers and purchasers. According to Paim *et al.* (2011) the health system in Brazil can be separated into three subsystems: the public system, represented by SUS; the private health system, which includes for-profit and non-profit services; and private health insurance, which offers various types of health plans, insurance premiums and tax subsidies.

### **1.4.1 Public Health system**

The public arm is organised on a hierarchical basis (federal, state and municipal) that nevertheless stresses the importance of significant decentralisation. At the municipal level, local authorities are responsible for health care delivery.<sup>18</sup> The state and federal levels provide for technical and financial support within the context of central government's control of the global budget, define national health policies and priorities and oversee intra-governmental relationships. The control of overall funding by the central government thus has implications for what, in terms of provision and access, can be achieved at municipal and state level. Figure 1.1 shows an overview of the instances and administration levels that compose SUS.

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<sup>18</sup> In Brazil the municipal health secretariat is the local health authority.



**Figure 1.1- SUS agreement forums and mechanisms for operation and coordination**

Although in the course of this work I will give detailed information regarding the structures and actors of the public health system it is useful to have a picture of the complex mechanisms that govern the operation of SUS. I depicted SUS operations in three sections: the executive bodies and corresponding representative boards (represented by the Ministry of Health, the state health secretariats and the municipal health secretariats, and their representative boards)<sup>19</sup>; social participation (represented by the health councils and health conferences at the three levels)<sup>20</sup> and the interfederative relations (represented by the bipartite and tripartite intergovernmental

<sup>19</sup> Representative boards are: CONASS - the National Council of State Health Secretaries; CONASEMS - National Council of Municipal Health Secretaries, and COSEMS – Municipal Council of Health Secretaries.

<sup>20</sup> Social participation in SUS is provided by the National Health Council-CNS; State Health Councils-CES, and Municipal Health Councils-CMS. These councils in each government tier coordinate the corresponding Health Conference: National Health Conference-ConfNS; State Health Conference-ConfES, and ConfMS-Municipal Health Conference.

commissions).<sup>21</sup> Figure 1.1 shows the three levels of the federation and the corresponding structure in each level for provision of services, social participation and the representative boards that participate in the interfederative forums of agreement.

#### **1.4.2 The private health-care and private health insurance subsystems**

Historically, limitations on health care provision by the public sector have led to the development of an important private sector consisting mainly of medical practices, specialist diagnostic and therapeutic clinics, private hospitals and health insurance companies.

Interface with the public sector is related to the provision of services contracted-out by SUS to complete the supply of health care. SUS infrastructure is insufficient to meet the demand for public services. As a result, the private sector is financed by public and private sources. A major part of the private sector consists of private health plans and the health insurance market. Public and private corporations' employees are the majority of the users of these private health plans where the insurance is co-financed by the employer and employee. An incongruent feature of the system is the fact that if you are a public employee or civil servant you are more likely to have private health insurance than relying on the public health system. In 2008, the proportion of the Brazilian population holding health insurance represented 21.4% (Ministerio da Saude, 2010). Again, the social and economic inequalities are reflected in the distribution of health insurance coverage. According to the Ministry of Health, the Southeast region concentrated the highest rate of population coverage by private health care plans (28.1%), with about 22.5 million beneficiaries, of whom 13.7 million were in São Paulo state alone.

The network of services for diagnosis and therapeutic support is made up almost exclusively by for-profit private facilities. In 2002, the public sector had only 5% of the network facilities, whereas the private sector held 92%. Within this network, however, only 35% of facilities provided services to SUS, compared with 91% selling services for private health insurance. The fact that the health system is not merely dual, but largely based on the private network facilities, has implications for the operation of SUS. The private services prefer to sell their services to health

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<sup>21</sup> The CIT-Tripartite Intergovernmental Commission has representatives of the Ministry of Health, CONASS and CONASEMS; and the CIB-Bipartite Intergovernmental Commissions take place in each state of the federation and bring together the municipal health secretaries and the state health secretary.

insurance corporations, except in procedures for which the amounts paid by SUS are greater than those paid by the private sector (Menicucci, 2009). Conversely, the provision of expensive and complex health treatments, even for the beneficiaries of private health insurance, falls mainly on the public system, which provides for transplantation procedures, cancer treatments, heart surgery and assistance in long-term haemodialysis. Regarding this pattern of user's behaviour, it would be reasonable to conclude that SUS is contributing to widening the gap between SUS users and citizens with private health plans. Contrasting with SUS users who struggle to gain access to the health service, clients of private health plans have access to specialist clinics and diagnostic services. With these diagnoses in hand, indicating the necessity of a complex surgery, private health plan holders can bypass the long SUS queue for further diagnostic exams (magnetic resonance imaging, for instance). They will most probably have their expensive surgery before those that only have access to SUS services.

These inequalities in access to treatments and services, inherent to SUS, also contribute to the issues surrounding access to medicines. In the next section I will discuss how policies related to pharmaceutical assistance have been developed within SUS.

## **1.5 Development in pharmaceutical policy**

Against the backdrop of SUS and its current state of development, this section discusses the key policies, programmes and initiatives that shaped the pharmaceutical framework in Brazil with regard to supply of basic medicines. In doing so, I will explore six important initiatives within the development of basic pharmaceutical assistance in Brazil.

### **1.5.1 Adoption of essential medicine list**

The use of essential medicine lists was one of the first strategies employed in the construction of pharmaceutical policy in Brazil. The first list was established by Presidential Decree in 1964, and was previous to the WHO initiative that launched the model of essential medicine lists as a strategy to organise provision in developing countries, in 1977 (Bermudez, 1995). From the perspective of the production process, in Brazil, the initiatives to stimulate the development of the pharmaceutical

industry also date back to the 1960s and 1970s. In order to stimulate the development of the base chemical industry, the federal government created the Industrial Development Board (Bermudez, 1994). In 1971, these productive activities became part of the scope of the newly created Central of Medicines (CEME – *Central de Medicamentos*).

In 1975, that initial list of essential medicines was improved, including more drugs, and was renamed National List of Essential Medicines (RENAME – *Relação Nacional de Medicamentos Essenciais*) (Ministério da Saúde, 2010). RENAME was drawn up by CEME staff and listed 305 pharmaceutical substances covering 99% of the drugs needed by the population. The list was supposed to be periodically updated and was proposed to facilitate the rational use of medicines and to improve the procurement process. According to Castelo *et al.* (1991), the strategy of creating an essential drugs list allowed the government to procure medicines about 40% cheaper, both by buying in bulk and by buying generic brands.

### **1.5.2 CEME**

In the 1970s the activities relating to medicines were centralised at the federal level. CEME, established by the military government, was in charge of writing the essential drugs list, its purchase and distribution. The main objectives were the provision of pharmaceutical products for the population with low purchasing power, and the incentive of scientific and technological research in the chemical-pharmaceutical field. Additionally, CEME was to foster and improve the pharmaceutical industry, with emphasis upon pharmaceutical input production by the State (Paula *et al.*, 2009; Cosendey *et al.*, 2000). CEME was linked directly to the Presidency of the Republic, being at the mercy of ideological and political interests that sometimes diverged from its goals. In fact, the provision of the priority medicines listed by CEME was frequently deficient (Cosendey *et al.*, 2000). In 1974, CEME was transferred to the Ministry of Social Security as part of an organisational restructuring project of the federal government. The restructuring reduced CEME's activities to drug distribution only. In 1975, the government transferred to the Ministry of Industry and Trade the promotion and coordination activities aimed at chemical and pharmaceutical technology development, which previously were CEME's remit.

Despite the alleged strategic role of CEME in fostering the national pharmaceutical industry, those governmental changes and budgetary difficulties undermined the institution (Bermudez and Possas, 1995). Over 26 years (1971-1997) CEME remained responsible for the main activities related to medicine and pharmaceutical services in the country. The economic difficulties that marked the Brazilian economy, the low prioritisation of health and a sluggish bureaucracy, resulted in a budget that was too low for CEME's distribution programme. Thus, despite government efforts to improve the pharmaceutical services by implementing the list of priority medicines, supply of these drugs was precarious and deficient under CEME management (Bermudez, 1994). Examples that may confirm that deficiency are reported episodes of shortage of rifampicin for treating tuberculosis in primary health centres in variable periods of time (Castelo, Lopes Colombo and Holbrook, 1991).

Arguably, CEME was regarded as an important government initiative translated into a policy to improve the access to essential medicines. Nevertheless, this project ideally conceived to strengthen the national pharmaceutical industry achieved no substantial results due to conflict of interests between public and private sectors, among other reasons. The private view prevailed with the hegemony of transnational corporations in the Brazilian pharmaceutical market, and CEME gradually lost power until being abolished in 1997 (Kornis, Braga and Zaire, 2008).

### **1.5.3 Basic Pharmacy**

In 1987, when CEME was still responsible for distribution of medicines, the government created the Basic Pharmacy to address deficiencies in the provision of medicines (Cosendey *et al.*, 2000). This initiative was designed to provide drugs for primary care. The operational strategy was the distribution of a fixed set of 48 medicines, many of them produced by public laboratories. The medicines, selected within RENAME, covered the treatment of common diseases. Later, other drugs for treatment of chronic conditions were added to a total of 60 medicines. Standard sets of medicines were distributed in amounts sufficient to provide three thousand people with essential medicines for a period of six months. Distribution of this single set of medicines to the whole country (not taking into account the epidemiological differences of each region, among other things), however, resulted in the lack of some drugs and excess of others. This in turn caused waste but also shortages of specific medicines. This lack of planning in the production and distribution of drugs, associated with the discontinuities in later years, had prevented the expected outcome of the initiative (Cosendey *et al.*, 2000).

The abolishment of the pricing control of drugs by the federal government in 1992, and the consequent adjustment of prices by the pharmaceutical industry, generated a crisis evidenced by supply problems and significant increase in the sales price at that time (Bermudez and Possas, 1995). The sales prices of some essential medicines were up to 20 times more expensive compared to prices set by UNICEF (United Nations Children's Fund) and the WHO (Abbas and Bermudez, 1993). Accordingly, an abrupt rise of 54% in the prices of medicines between 1989 and 1999 (Serra, 1999; Bermudez and Possas, 1995), combined with the inefficiency and discontinuity in medicine distribution programmes, exacerbated access problems. The shortage in medicines affected, as expected, citizens with limited purchasing power and put additional pressure on the federal government (Cosendey, 2000).

CEME's closure in 1997 leveraged the process of reorganisation of pharmaceutical policy. New proposals were placed as a counterpoint to the centralised procurement and distribution of drugs charged by CEME (Gomes, 2003). The year that followed the deactivation of CEME marked a process of transition in which activities of procurement and distribution of drugs were fragmented among different organs of the Ministry of Health, going to the Executive Secretary of Ministry of Health, Secretariat of Health Surveillance, Department of Health Policy, and Department of Special Projects (Cosendey *et al.*, 2000).

#### **1.5.4 The Basic Pharmacy Programme**

Concomitantly with CEME's closure, in 1997, in order to increase the public pharmaceutical supply, the Ministry of Health created the Basic Pharmacy Programme (PFB – *Programa Farmácia Básica*). The programme was supposed to promote access to essential medicines for the population living in the poorest municipalities (Cosendey, 2000). This programme was structured along the lines of the Basic Pharmacy run in 1987 except for the size of the municipalities included, the medicines distributed, and the management, which was under Ministry of Health rule.<sup>22</sup> Like the previous initiative, the programme used a standard module of 40 essential drugs, which covered prescribed drugs to outpatients of primary care services, and drugs were distributed to municipalities with up to 21,000 inhabitants. This selection included 4,199 Brazilian municipalities except for the states of Sao Paulo, Parana and Minas Gerais, which had already initiated a process

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<sup>22</sup> The initiatives shared the same name except for the word 'programme'.

of pharmaceutical services reorganisation. As could be expected, this programme showed the same failures that the Basic Pharmacy had. A study of the implementation of this programme in five Brazilian states showed that the main criticism of local authorities was the inadequacy of the standard set of drugs distributed, which did not fit in with the differences in necessity according to the diseases' prevalence in each region (Cosendey, 2000). The author argues that the Ministry of Health lost an opportunity to engage the state level in the design of this programme. She argues that participation of the state health secretaries in this process could represent an important step toward the decentralisation of basic pharmaceutical assistance.

### **1.5.5 National Medicine Policy**

The context of precarious access, worsened by the marked social differences and the distribution of medicines without taking into consideration regional needs, boosted the discussion of the need for pharmaceutical policies capable of ensuring equitable access. These discussions were led by the National Council of State Health Secretaries (CONASS – *Conselho Nacional de Secretários Estaduais de Saúde*) in workshops sponsored in 1997 and 1998, and by the National Health Council (CNS – *Conselho Nacional de Saúde*) (Ministério da Saúde, Conselho Nacional de Saúde, 2005).

It would be reasonable to suppose that the process of negotiation, social participation and pressure that drove the creation of SUS would participate in forging a pharmaceutical policy. There was not, however, the same momentum in 1998 when the National Medicines Policy (NMP – *Política Nacional de Medicamentos*) was launched, as was the case in the health reform movement in the 1980's. Changes related to pharmaceutical assistance that culminated in the NMP were incremental and spread over about ten years since the creation of SUS. Social participation had no significant role in the elaboration of the NMP launched in 1998. In fact, the first major forum that provided an opportunity for social participation in the field only took place in 2003 in the First National Conference on Medicines and Pharmaceutical Assistance. Although decentralisation of pharmaceutical assistance was underway at that time, this theme appeared just three times in the Conference's final report. More evident in that report was the need to merge fragmented programmes and the integration of pharmaceutical assistance into SUS activities (Ministério da Saúde, Conselho Nacional de Saúde, 2005). The report of the First Medicines and Pharmaceutical Assistance National Conference argued that the NMP had pulverised the cycle of the pharmaceutical assistance into dozens of specific programmes, scattered in different departments of

the Ministry of Health, impairing its control and monitoring (Ministério da Saúde, Conselho Nacional de Saúde, 2005).

Other linked factors, such as disconnection of pharmaceutical assistance within SUS and the need to reorganise it, the lack of an updated standardised list of essential medicines, added to the precarious supply of drugs on an outpatient basis contributed to build an urgent case for the development of the NMP (Gomes *et al.*, 2001).

Within this perspective, the NMP was launched in 1998, drawing upon the principles and guidelines of SUS. This policy introduced what was called the reorientation of pharmaceutical care. NMP's basic premise was the decentralisation of acquisition and distribution of essential drugs.<sup>23</sup> The federal administration, from that moment, was responsible for the transfer of funds and provision of technical cooperation. The implementation of this new arrangement started the process of decentralisation of pharmaceutical assistance.

The NMP defined pharmaceutical assistance as a “group of drug-related activities designed to support the health demands of communities” (Ministerio da Saude, 2000b). Pharmaceutical assistance is a term created in Brazil to designate the health care activities involving drugs. According to Marin (2003), the definition of pharmaceutical assistance involves comprehensive, multi-professional and intersectoral activities connected to the management of services related to medicines in its various dimensions, with emphasis on the relationship with the patient, the community and health promotion. In this sense, the public delivery and management of medicines by SUS is also part of pharmaceutical assistance.

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<sup>23</sup>But the NMP has a broad scope that includes, briefly, the following guidelines: adoption of the essential medicines list (the RENAME) to inform the drugs to be prescribed, purchased, and delivered; sanitary regulation of medicines; promotion of rational use of medicines; the scientific and technological development; promoting the production of medicines; ensuring safety, efficacy and quality of medicines; and the development and training of human resources involved in pharmaceutical care (Ministério da Saúde, 2001).

It is worth noting that the decentralisation provided in the NMP, in 1998, was limited to the management of the medicines for primary care. In reality, decentralisation only started in 2005 when funds were transferred to subnational levels.

### **1.5.6 Popular Pharmacy Programme**

In 2004, taking an additional measure in the process of implementing the access to medicines, the Federal Government put into operation the Brazilian Popular Pharmacy Programme (FP – *Programa Farmácia Popular do Brasil*), which emerged as one of the steps taken towards the expansion of access to medicines. The programme is considered an innovative policy that established the co-payment scheme for the purchase of medicines in public or community pharmacies (Ministerio da Saude, 2005b). The programme operates independently and in parallel to the provision of public medicines and is regarded as a strategy for complementary access to drugs. Pinto (2008), argues that the initiative can be regarded as federal interference in a decentralised system. Analysing the implementation of the programme, the author claims that the effectiveness of decentralised pharmaceutical assistance managed at local level is being questioned. The model of centralised management of basic medicines is returning, as it is considered more effective. Reinforcing his arguments, the author asserts that the implementation of the Programme gives the federal level the chance to keep activities and products standardised throughout the country, and provide gains from large-scale purchases. The Ministry of Health, in February 2011, went a step beyond increasing investments in the Popular Pharmacy programme in order to expand the free access to essential medicines (Ministerio da Saude, 2011). The drugs to treat diabetes and hypertension became available free of charge upon the presentation of a prescription at community pharmacies in the programme. It is worth stressing that co-ordination, management and financing are centralised at the federal level.

In summary, the elements discussed here impacted on the Brazilian health system, changing public services from having restricted access and centralised management during the years of military rule to experiencing universal coverage and decentralisation resulting from the reforms introduced in the re-democratisation period. The implementation of decentralisation was incremental and incorporated elements to improve the role of subnational actors in the provision of health services. Following the move, the management of basic pharmaceutical assistance was also transferred to municipalities in 1998. Since then there have been multiple efforts by the three government tiers to improve the provision of medicines by the municipalities. The legal framework and financial

incentives were focused on strengthening the role of subnational actors in this process. This trend of decentralisation might be changing, however. The FP programme is a clear indication that the federal government is heading in the opposite direction. Having contextualised the pharmaceutical assistance within the Brazilian public health system, in the next section I will discuss my research questions in this investigation.

## **1.6 Research problem and research questions**

This thesis explores the relationship between decentralisation, recentralisation, and access to medicines in Brazil. My central interest is in how the simultaneous processes of decentralisation and recentralisation have affected the access to medicines. To answer this question, and to explore how political and power dynamics influenced the provision of medicines, this research will investigate the following questions:

1. How has the decentralisation of provision of basic medicines taken place? Who were the main actors in this process? What were the main rationales?
2. How has the federative arrangement of the country affected the decentralisation of public provision of medicines in Brazil?
3. How, and to what extent – if at all – has the public provision of medicines improved after decentralisation?
4. What did the recentralisation of provision of medicines (represented by the Popular Pharmacy Programme) mean to the decentralised context of pharmaceutical assistance?

Consequently, my research used two different kinds of sources, each informing and shaping the others. An initial “policy review” and interpretation of public domain policy documents, associated commentaries and academic publications (summarised in Chapter Two, the literature review) helped to identify key interviewees whose insights might be particularly illuminating about the dynamics and progress of the decentralisation of pharmaceutical services in Brazil. In addition, semi-structured interviews (see below) were conducted with key interviewees across the three tiers

of government (federal, state and municipal) who participate in the formal forums of agreement within the policy-making for pharmaceutical assistance provided in SUS.

My thesis makes the following contributions to the existing literature: firstly, it contributes to the discussion about the limitations of decentralisation, more specifically regarding pharmaceutical assistance in federative states; secondly, it offers a new perspective on the understanding of the implications of adopting decentralised or centralised strategies for the provision of essential medicines; and thirdly, it helps to clarify the mechanisms which govern federative relations and their progress in relation to pharmaceutical assistance in SUS as a consequence of the decentralisation process.

## **1.7 Structure of the thesis**

The study is divided into eight chapters, including this introduction. This *first chapter* discusses the political context within which Brazilian health reform happened. It also outlines the development of pharmaceutical policy under the decentralisation process, highlighting the unresolved issues regarding access to essential medicines.

The *second chapter* presents a review of relevant literature and reflects on the definition of decentralisation regarding public administration, as well as current debates around decentralisation and centralisation of health policies. This chapter also gives a brief account of the political justification for adopting decentralisation policies, particularly in relation to health policies. The chapter then turns to the contemporary debates concerning the decentralisation-recentralisation policies in the field of pharmaceutical assistance within Brazil. That debate is followed by an overview of public provision of and access to essential medicines. The chapter finishes with a more general review of theoretical and analytical contributions concerning the policy process and “power”.

*Chapter three* describes the study's design and methodology, providing a conceptual rationale for the approach taken to the research as well as a detailed description of the methods used. This chapter also details the source of data used and the collection method.

*Chapters four, five, six and seven* primarily use the narratives presented by key actors involved in policy-making and decision in Brazil to explore their views and perceptions of the changes introduced by decentralisation in the public provision of essential medicines. Those views are discussed in conjunction with the related policy documents and legal framework for pharmaceutical assistance. Each of these four chapters aims to answer one of the research questions, as detailed next.

*Chapter four* mainly uses the data I gathered in my interviews to explore how the decentralisation of provision of basic medicines has developed and who the main actors and rationales in this process were. The chapter is specially focused on decentralisation and centralisation of public provision of essential medicines. It presents views of how decentralisation happened, motivations and limitations of the process as well as regional differences in the implementation. The kind of bottom-up policy-making introduced by decentralisation is also discussed in conjunction with the legal and policy framework.

*Chapter five* explores how the federative arrangement and consequent intergovernmental relations have affected the decentralisation of public provision of medicines. The chapter presents views on the developments and advances of intergovernmental relations in the process of decentralising pharmaceutical assistance. It also considers the process of negotiation which takes place in the forums of agreement, and how fulfilment of the agreements affects the development of pharmaceutical assistance.

*Chapter six* discusses the changes in the public provision of medicines after decentralisation. The chapter analyses pharmaceutical assistance and access to medicines. The main points discussed are the consequences of decentralisation in the shaping of pharmaceutical assistance and the perceived impact on access. Limitations in assessing the impact on access to medicines and other barriers are also discussed in this chapter.

*Chapter seven* explores the implications of the Popular Pharmacy programme for the decentralised context of pharmaceutical assistance. The chapter discusses the changes of the direction taken by the federal government in the decentralised provision of medicines. The characteristics and special features of the Popular Pharmacy Programme and its role within the public provision of essential medicines were also discussed. Drawing upon the analysis of my interviews as well as relevant policy documents I discuss how this programme entered the policy arena, its repercussions in federative relations, and its impacts on access to medicines.

*Chapter eight* presents the conclusions, summarises the findings, and offers the closing remarks.

**CHAPTER TWO**  
**LITERATURE REVIEW**  
**DECENTRALISATION, POWER, AND ACCESS TO MEDICINES**

**2.1. Introduction**

This thesis explores how the decentralisation of the provision of medicines developed in the last decade in Brazil, and its implications for access to medicines. In Chapter One I explained, briefly, the context in which health reforms and decentralisation of health services occurred, and how SUS - the Brazilian public health system - currently works. In this context, I explained the decentralisation of pharmaceutical assistance and the key elements related to the operation of that area. In this Chapter I will provide an overview of a range of literature analysing decentralisation processes, policy-making, power and access to medicines in Brazil.

Decentralisation, in broad terms, entails the shift of power from central government to organizations closer to the operation, provision and recipients of services. Rationales for decentralisation are often premised on a view that smaller organisations are, intrinsically, more responsive and accountable than larger organisations (Saltman, Bankauskaite and Vrangbaek, 2007). In the context of health reforms in developing countries, decentralisation was viewed initially as an administrative reform which would improve efficiency and quality of services and later as a means of promoting democracy and accountability to the local population (Bossert, 1998). A number of advantages have been identified to justify this transfer of power, particularly in developing countries (Rondinelli, 1980). Decentralisation is also receiving increased attention as a potential tool in the fight against poverty (Jutting *et al.*, 2004; Litvack, Ahmad and Bird, 1998). Efficacy of decentralisation as a tool for improving social standards, however, is argued not to be appropriate to those countries where mitigation is most needed. A review of the experience of 19 countries suggests that the potential effects of decentralisation in poverty alleviation are dependent on the stage of the country's development (Jutting *et al.*, 2004). According to the authors, decentralisation most probably would increase poverty rather than reduce it in poor countries where the state lacks the capacity to fulfil its basic functions. In the case of Malawi, the authors argue that the depth of poverty<sup>24</sup> is an obstacle to democratic participation, which is one of the aspects associated with poverty alleviation. Jutting *et al.* (2004:44) also argue that in Nepal, considering

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<sup>24</sup> Metrics for depth of poverty indicate how far below the poverty line a poor person's income falls (Coudouel, Hentschel and Wodon, 2002).

the strong elite capture,<sup>25</sup> the high level of corruption, and “considering the existing power distribution (feudalistic and elitist leadership in rural Nepal), decentralisation has the inherent danger of legitimising and perpetuating existing power structures and exploitation”. Other perceived disadvantages of decentralisation, such as increased disparities and undermined efficiency, have also been described in the literature (De Vries, 2000; Prud'homme, 1995). Some scholars claim that decentralisation does not improve equity, quality or efficiency of services and that it even has the opposite effect due to financial constraints and supply-side failures (Kristiansen and Santoso, 2006; Tang and Bloom, 2000). In the late 1980s, basic health services were devolved to the lowest level of government in China. Tang and Bloom (2000) showed that services provided by health centres in rural areas deteriorated after decentralisation. The authors argue that changes in financial management, rather than increasing funding for health centres, resulted in severe financial constraints. Additionally, dissatisfaction with changes introduced by decentralisation caused a significant exodus of highly trained personnel from rural areas. The shortage in personnel led to recruitment and employment of less qualified people, resulting in falls in efficiency and quality of services provided by health centres. Such controversies attest to the complex nature of the aim of decentralising functions and services, and of the evaluation of such attempts. This complexity and uncertainty informs the purpose and content of this chapter – a review of literature relevant to the research with a particular focus on the topics and perspectives most relevant to reforms of pharmaceutical assistance in Brazil.

More specifically, in this chapter I employed a *realist* perspective in the view of Pawson *et al.* (2005) for the identification and categorisation of sources in the literature. The authors argue that large-scale policy reform in fields such as health and education rarely involves the formulation of wholly coherent and focused interventions designed to bring about clearly defined and measurable effects. Instead, systemic interventions are often grounded in a theory or hypothesis about the expected change that is held by some actors (rather than an uncontentious description of cause and effect). In a second respect, effects, whether intended or not, will often reflect the motivations and expectations of individuals and groups involved in the implementation of an intervention. Successes and failures of interventions are, in a certain respect, explained by personal choices and reasoning adopted by the actors involved. There is no reason to suppose that there will be coincidence in reasoning and personal choices among such actors, particularly if they operate within and across different tiers and institutions in the state apparatus. These differences in choices could hinder the implementation and explain, at least partly, some of the failures. Thirdly, interventions such as large-scale decentralisation do not occur in a ‘vacuum’ but, instead,

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<sup>25</sup> Elite capture occurs when the management of resources is shifted from the group that was intended to manage the resources, to an elite (Wong, 2010).

necessarily reflect many other factors of an ‘open system’, such as the distribution of political power, resources and the impact of private sector activity. Finally, in a fourth related aspect, policy interventions may be regarded as changing the conditions in which they were originally introduced. Thus, the reception and consequences of the same policy over time are altered as a consequence of policy learning (Pawson *et al.*, 2005: 23). In response to these observations this review of the literature reflects an initial collation and overview of relevant sources followed by their categorisation under topics judged most appropriate to the research reported in this thesis. The topics here elected are: decentralisation, power and access to medicines.

In order to explore these three topics, I will organise this chapter in six sections. After this introductory section, the second section reflects on the definition of decentralisation with particular reference to public administration and, more specifically, to the provision of public health services. This section also focuses upon current debates about trends in decentralisation and recentralisation and, in so doing, gives a brief account of some experiments across Europe and Latin America. The third section turns to the political justifications, the rationale, for adopting decentralisation policies in general and, more specifically, in relation to health services (highlighting the differences between developed and developing countries). The chapter’s fourth section provides a more general review of theoretical and analytical contributions concerning the policy process and *power*. Before the conclusions, section five overviews the situation of access to medicines in Brazil.

## **2.2 Decentralisation’s conceptual framework: definitions, key issues and debates**

Decentralisation is a highly complex process that has generated interest in a wide range of disciplines. There is extensive literature on this topic in various academic branches including politics, public administration, health services research, economics, management, sociology and organisational studies. This section focuses on the following aspects of decentralisation: 1) the definitions and difficulties entailed in the concept of decentralisation when it is applied across a wide range of contexts; 2) the complexity of assessing the impact of decentralisation policies and initiatives; 3) the political and financial dimensions of decentralisation, and 4) the outcomes of decentralisation.

### **2.2.1 Definition and analytical frameworks**

Decentralisation is a difficult term to define and has been understood in multiple ways (Bankauskaite and Saltman, 2007; Pollitt, Birchall and Putman, 1998; Mills *et al.*, 1990). Many

scholars agree that defining and measuring decentralisation is challenging (Saltman, Bankauskaite and Vrangbaek, 2007; Levaggi and Smith, 2005). Bankauskaite and Saltman (2007:2) state that “decentralization in practice represents many things to many people” referring to many variants of decentralisation that operate in Europe. The term encompasses political, fiscal and administrative dimensions and has been linked, traditionally, to the public administration field. The different ideas of what constitutes decentralisation are sometimes inconsistent and contradictory. Bankauskaite and Saltman (2007) argue that a particular divergence arises when definitions of decentralisation derived from public administration are applied to the health sector. Mills *et al.* (1990) concur and observe that the public administration literature tends only to mention the health sector superficially when discussing decentralisation and that, in turn, analyses of the health sector often neglect its relationship with broader areas of government administration. Moreover, still according to Bankauskaite and Saltman (2007), interpretation of the outcomes of decentralisation policies also often generates controversy. They argue that authors’ own biases may lead to a focus upon either positive or negative outcomes.

Accordingly, efforts to define and delimit the idea of decentralisation have generated a large sub-literature related to public administration, fiscal and political fields (Bossert, 1998; Mills *et al.*, 1990; Rondinelli, 1980). Definitions of decentralisation usually emphasise the transfer of power to planning, making decisions and managing public functions from the central level to lower levels in the government system (Saltman, 2003). Likewise, the topic has spurred the literature on analytical frameworks to examine the relationship between processes and types of decentralisation and actual outcomes or performance in the health sector.

The best known framework for analysing decentralisation in the field of public administration is that of Rondinelli (1980) who proposes four forms of decentralisation according to the degree of authority devolved and the type of actors to whom the authority is transferred: deconcentration, delegation, devolution, and privatisation. This public administration approach was first introduced for evaluating broad processes of decentralisation in developing countries but was also applied to health systems in an influential work conducted by Mills *et al.*(1990). These four types are typically found within the administrative form of decentralisation. The types of decentralisation, in addition to reflecting the degree of power enjoyed by the local level, are also related to legal frameworks because policies are often based upon constitutional amendments or national laws (Mills *et al.*, 1990). In short:

*Deconcentration:* A shift in authority to regional or district offices within the structure of a government ministry. De-concentration is seen as the

least extensive form of decentralisation since it only involves the transfer of administrative authority (Mills *et al.*, 1990). A district level office of the Ministry of Health is an example of de-concentration in the health sector (Mills *et al.*, 1990).

*Delegation:* The transfer of services and responsibilities to semi-autonomous agencies. This is related to the transfer of managerial responsibilities for defined functions and in health systems has been employed, for example, in the management of teaching hospitals or to provide health services for insured workers (Mills *et al.*, 1990).

*Devolution:* A shift in authority to state, provincial or municipal governments. Devolution creates or strengthens sub-national levels of government with substantial independence from the central level and is related to a significant redefinition of a set of roles that may entail marked structural reforms (Mills *et al.*, 1990). It is claimed that responsibilities for health when devolved to local government often entail issues of budgetary constraint, coordination and cooperation regarding the provision of specialised services (Mills *et al.*, 1990).

*Privatisation or transfer to non-government organisation:* Ownership is shifted to private entities, usually with a contract to define what is expected in exchange for public funding. For Bankauskaite and Saltman (2007), privatisation is “when tasks are transferred from public into private ownership”. This might also include the outsourcing of particular services.

Although widely employed, this fourfold classification framework has not generated widespread consensus. There are, for example, disputes over whether de-concentration, devolution and privatisation should be considered legitimate forms of decentralisation (Falleti, 2010; Bankauskaite and Saltman, 2007). The usefulness of Rondinelli’s framework has been also challenged by Exworthy *et al.* (2010), who argue that it cannot be applied in cases where decentralisation extends to the level of individuals (patients or staff) due to an exclusive focus upon institutional actors in the context of decentralisation. As the researchers remark, the categories do not consider the specific objects of decentralisation and do not conceptualise or enable the measurement of the level of autonomy transferred to local governments.

Decentralisation has become the usual strategy adopted by health sectors in many countries across Europe in a restructuring process that has accelerated since the Second World War, producing an important strand of the literature specifically addressing the decentralisation of health systems (Saltman, Bankauskaite and Vrangbaek, 2007:2). In the last two decades many different approaches to the topic have appeared in the literature. Four of these analytical approaches that I consider useful to this thesis, arranged in chronological order, are outlined in Table 2.1. The table illustrates the diversity of aspects considered, which link in with the complexity of the process, showing that no single approach is capable of reflecting all aspects involved.

**Table 2.1 - Decentralisation in health systems frameworks**

Author	Framework	Reasoning
Bossert, 1998	Decision space	Defines decentralisation in terms of the set of functions and degrees of choice (narrow, moderate or wide) that are formally transferred to local officials. Evaluates incentives; local government characteristics; whether or not local officials innovate; and then assesses the impact of local choices on performance.
Levaggi and Smith, 2004	Economic	Deals with transfer of financial and policy powers. Emphasises the role of information asymmetry in determining optimal governmental structure and the role of central governments in ensuring that public services accommodate any valued spillover effects (clinical training and research, public health, inequalities, information, macroeconomics factors).
Saltman and Bankauskaite, 2006	Functional	Analyses decentralisation in terms of three functional dimensions: political, administrative, and fiscal.
Peckham, 2008; Exworthy, 2010	Arrows	Focuses on the content of decentralisation (the 'what' issue) and identifies the scope of decentralisation (from 'where' to 'where?'). Examines the processes of centralisation/decentralisation as multiple processes that occur concurrently.

The decision-space framework proposed by Bossert (1998) is a modification of the principal agent approach that was developed by economists. The principal agent approach was first used to analyse federal intergovernmental transfers but was also applied in health care to explore the relationship between provider and patient. The decision-space framework centres on the extent to which the

expansion of choice transferred in the decentralisation process can be seen to contribute to the achievement of the goals associated with decentralisation (Exworthy *et al.*, 2010). The framework distinguishes between three main elements - the amount of choice transferred, the types of choices local officials make, and the impact of these choices upon performance (Bossert, 1998). In this framework the decision-space is applied across functional areas of the health system and is “quantified” into three categories (narrow, moderate or wide). The transferability of the approaches developed by both Bossert and Rondinelli is, however, arguable, because both focus on developing countries (Peckham *et al.*, 2008). But the decision space model is also suitable for observing the dynamic nature of the distribution of authority between central and regional/local institutions.

The framework proposed by Levaggi and Smith centres upon an economic perspective on two issues that they consider “common for all types of decentralisation: transfer of finance powers and transfer of police powers” (2005:224). An apparent strength of the model - a well-defined focus - might also be seen as a weakness because it is greatly concentrated on the financial dimension of decentralisation (excluding other important influences on authority and legitimacy). Despite the importance of financial factors involved, an economic framework alone is unlikely to provide sufficient insight into the complex task of assessing decentralisation in the context of the health field.

Considering that a more targeted approach is needed, Saltman and Bankauskaite (2006) argue that approaches to decentralisation in the disciplinary fields of public administration and economics tend to be oriented to the public sector in general and do not consider particular forms of decentralisation specific to the health sector. For example, it is not uncommon for two or more organisational forms of decentralisation to co-exist in a particular health care system. To facilitate the analysis of such arrangements the authors propose a functional framework that takes into account three key dimensions - political, administrative and fiscal. A better understanding of the potential advantages and disadvantages of decentralisation and the possibility of assessing the strategies adopted are the main arguments used to support the functional model. Saltman and Bankauskaite concede that their approach, because it was developed with tax-funded health systems in mind, requires further elaboration in order to be applicable to countries with new private arrangements in the health sector.

Pollitt *et al.* (1998:6), drawing on a number of contributors, state that “decentralisation involves the spreading out of formal authority from a smaller to a larger number of actors”. The authors thus equate “political” decentralisation with the devolution of authority to elected representatives.

According to DeVries (2000), the introduction of political decentralisation within a health care system can entail advantages and disadvantages for policymakers. The disadvantages, seen from an economic point of view, centre upon the potential inefficiency and duplication associated with a myriad of small service providers.

In a fourth respect, the arrows framework (Exworthy *et al.*, 2010; Peckham *et al.*, 2008) has been proposed as a way to analyse decentralisation and recentralisation movements within the British National Health Service and to explore the possible links between decentralisation and performance. It is a two-dimensional framework designed to address the ‘what’ and ‘where’ of decentralisation. The horizontal axis is the hierarchy in which decentralisation takes place (ranging from global institutions to individuals). This axis explores and indicates the ‘from where’ and ‘to where’ dimensions through the use of directional arrows. The vertical axis considers ‘what’ is being moved between different levels within a hierarchy and gauges the impact of these transfers upon performance through the concepts of input, process and outcome. The depiction of performance is descriptive – the framework itself does not evaluate the quality of performance attributable to transfers.

Each of the frameworks presented has some validity and provides some insight into key issues of decentralisation. Considering the complexity of decentralisation, the importance of context and the limitations presented by the different analytical frameworks, Peckham *et al.* (2005) observe that “there is limited applicability of any single framework that can be applied in all circumstances”. In sum, decentralisation studies have been dominated by multiple perspectives and, overall, the proposed frameworks or approaches of analysis were developed in parallel rather than building on each other. Two important questions thus remain unanswered. First, what are the most appropriate strategies, if any, to assess decentralisation in the context of health services? Second, how can we relate decentralisation to issues of performance? These are sound questions even if in this thesis I am not conducting policy analysis. These issues are closely related to my central question about how decentralisation has affected the public provision of medicines in Brazil, and I will return to this when discussing my research design approach in Chapter Three.

### **2.2.2 Political and financial dimensions**

Beyond the issues of defining decentralisation and the difficulties in its measurement, the political and financial aspects involved also involve complexity and ambiguity. In these areas the predilections of the analyst are often considered a variable in itself (Bankauskaite and Saltman,

2007). Similarly, political perspectives are intrinsically linked to decentralisation because it often concerns the distribution and sharing of power. In more detail, Bankauskaite and Saltman (2007) perceive three factors that shape the political backdrop to decentralisation: institutional structure; social and cultural values; and governance mechanisms. Indeed, there appears to be a degree of agreement among many scholars that the different meanings, goals and evaluations associated with reforms are central to their understanding and evaluation (Falleti, 2010). Conversely, this emphasis on context is considered a disadvantage for Peckham *et al.* (2008). The latter argue that it is the contextualised nature of interpretive frameworks that hampers their applicability beyond specific environments.

Although decentralisation has many disputed points around definitions, goals and outcomes, scholars agree on the importance of knowing the context, different meanings and aims that drive a particular reform if one seeks to understand how decentralisation happened, as I do. How these concepts informed my research design will be discussed in more detail in Chapter Three.

### **2.2.3 Decentralisation outcomes in health**

The difficulty of having multiple frameworks, an important unresolved question, affects the outcomes of the changes in a health system as a result of decentralisation. Broadly, there is little agreement about the outcomes that decentralisation should produce and the evidence from the literature is mixed (Bustamante, 2010; Saltman and Bankauskaite, 2006). Bankauskaite and Saltman (2007) add that when the focus turns to the implementation of such decentralisation policies the results are even more inconsistent. For some authors, contrary to the supposed advantages, there is little evidence that decentralisation has led to improvements in equity, quality or efficiency in local services or to an increase in local funding (Pariyo *et al.*, 2009; Tang and Bloom, 2000). In Uganda, a study of the devolution of powers to allocate resources and deliver services, including health, concluded that there was little impact on access to health care (Pariyo *et al.*, 2009). After the decentralisation process in that country, the use of public health services increased, but the private for-profit sector still provided most of the formal health care. Moreover, the costs and travel entailed remained significant barriers to the use of health services by the poorest patients. The power to allocate resources alone was not sufficient to enhance equity and access to health services. Another study - concerned with the relationship between decentralisation and equity in health and health care in the largely decentralised Canadian health care system - suggests that income-related inequalities in health care utilisation are more influenced by differences between poorer and wealthier provinces than by the form and extent of decentralisation (Jimenez-Rubio, Smith and Van Doorslaer, 2008). The research, claim the authors, points to the

need for central government intervention to balance resources between provinces rather than further structural reform. This argument on the role of regional differences in decentralisation is of particular importance to inform my discussion in Chapter Four on how regional differences shaped the implementation of decentralisation in the Brazilian health system.

Conversely, positive impacts of decentralisation have been cited, for example, in a child immunisation programme in developing countries and also in relation to achieving equitable per capita financial allocation between municipalities in Colombia and Chile (Khaleghian, 2004; Bossert *et al.*, 2003). In this last regard, financial decentralisation that took place in these two countries was analysed using a decision space framework. Findings suggested that those policies had a positive effect on health resource allocation in terms of equity (Bossert *et al.*, 2003). In Colombia, the study reports, a population-related formula for resource allocation appeared to be an effective mechanism for making expenditure more equitable. The scholars remark that a more balanced per capita allocation was obtained by the use of a horizontal equity fund that redistributed local revenues between municipalities in Chile.

It is worth noting in this review that this form of decentralisation of resources was not, however, capable of balancing the regional differences in Brazil, as data from my interviews suggest. SUS uses this per capita criterion in funds allocation, but metropolitan areas or the more developed cities within a geographical area still attracting patients in search of more complex or emergency treatments. There is a saying in Brazil that ‘the best hospital (in less developed regions) is the ambulance’. It is common practice for mayors or local health authorities to send patients to be treated in hospitals in the state capital or other cities around the region. As the resource funding is based on per capita values, this is claimed to cause a financial imbalance and overcrowding because those cities have to treat more patients than they were prepared or received money for.<sup>26</sup>

As the examples above illustrate, the empirical evidence is difficult to compare because the outcomes of decentralisation are influenced by the context of the reforms. Similar programmes will produce contradictory results depending on where and when they are implemented. In order to better grasp the understanding of the implications of decentralisation, a key issue that also needs to

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<sup>26</sup> This issue of ‘migration’ of patients searching for health treatment is very often broadcast in the media. I would say that nobody in any region of the country would be surprised at hearing this kind of news. The financial burden caused by migration of patients is usually a point of contention, involving municipal, state and federal governments. An example of this situation is a recent case involving three states of the Northern and Midwestern regions. For more details see: <http://casacivil.to.gov.br/noticia/2013/4/12/pacientes-de-outros-estados-geram-onus-de-r-4-milhoes-ao-tocantins/> [retrieved 15/06/2013].

be analysed involves the reasons used to justify decentralising or centralising measures. This point is addressed in the next section.

### **2.3 General rationales for decentralisation**

Decentralisation has been one of the most recurrent themes in governmental reforms over the last two decades (Falleti, 2010; Boex and Simatupang, 2008; Atkinson and Haran, 2004; Bossert, Larrañaga and Ruiz Meir, 2000; Collins, Araujo and Barbosa, 2000). A broad range of rationales emerged from these changes, including efficiency in the provision of services; reducing costs and strengthening accountability; addressing local needs; bringing government close to the people and improving popular participation (Dubey, 2003; World Bank, 1997). The rationales can be separated into political and economic arguments. If we take into consideration the decentralisation of the health system in Brazil, both arguments were in place but used by different groups. From one side the claims of the *sanitarista* movement linked decentralisation with political arguments related to the re-democratisation of the country (Doimo and Rodrigues, 2008). On the other side, neo-liberal reforms brought a new rationality to public management, involving reduction of the role of the state which went to exercise regulatory functions withdrawing from direct provision of services. Within these views, financing was also separated from service delivery, which became the responsibility of subnational actors.

The political arguments appeal to theories or claims that decentralisation improves democracy by bringing the government closer to the people (Falleti, 2010). In many countries the discussion of increased democracy is linked to the political move to decentralisation. Decentralisation is associated with the promotion of local democratic involvement and distribution of political power, which could reduce the potential for corruption. Within the arguments relating to economics, change is often justified with reference to the theory of fiscal federalism (Saltman, Bankauskaite and Vrangbaek, 2007). The tenets of this theory include a view that local government should, where possible, provide and fund the public goods and services consumed within their jurisdictions (Oates, 1999). Decentralised provision, it is argued, increases local economic welfare because services and public goods can be tailored to particular preferences and needs. Oates (1999) also refers to the Tiebout (1956) model wherein intergovernmental competition facilitates different local government taxation and expenditure policies that will encourage citizens to ‘vote with their feet’ - a direct expression of political preferences that discourages inefficiency (Bardhan, 2002). Additionally, in a third, related, regard it is claimed that decentralised systems act as a *de facto* or *de jure* limit on central government interference with the supposed benefits and savings that accrue

from such competition. Similar arguments suggest that decentralisation improves the monitoring and supervision of local government because local politicians have more of an incentive to respond to local demands than national legislators. Moreover, it is claimed that local politicians can reasonably be assumed to be better informed about local preferences and needs (Aguilar, 2006).

The degree to which these rationales are applicable to less economically developed countries has however been questioned (Bardhan, 2002; Prud'homme, 1995). Key differences between these countries and more developed economies could hamper the relevance of such reasoning in developing countries. These differences include: lower citizen mobility; less effective monitoring of public administration; weaker institutions of local democracy and mechanisms for political accountability; a greater case for the redistribution of resources to disadvantaged groups or regions; the impact of poverty on homogenised preferences; a non-linear relationship between taxation and service provision; plus asymmetric technical and administrative capacities between levels of government (Bardhan, 2002). Levaggi and Smith (2004) add that the optimal degree of decentralisation is likely to vary between different health system functions. Primary care and chronic care services are perhaps more suited to local discretion and would benefit more from decentralisation than secondary care services.<sup>27</sup> Conversely, in order to enhance local coordination and efficiency it may be necessary to purchase or commission health services through just one agency. The authors note that the appropriate level of decentralisation in health care is a difficult policy judgement that will often involve a trade-off between conflicting objectives. These discussions about appropriate levels of decentralisation will be particularly useful in Chapter Seven when I analyse a centralised programme of provision of medicines which emerged within the decentralised model adopted in Brazil.

In summary, the main political and economic rationales in relation to decentralisation have been reviewed briefly. Political arguments tend to equate decentralisation with distribution of power, enhanced democracy and citizenry. Economic arguments, reflecting fiscal federalist ideas and more general perspectives in theories of political economy suggest that decentralisation increases efficiency in the allocation of resources. Against the background of these general perspectives for decentralisation I will now focus more specifically on decentralisation in the health sector. For this

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<sup>27</sup> Primary care is the first point of consultation for all patients within the health care system, being a patient's main source for regular medical care. Primary care is intended to provide a broad spectrum of preventive and curative care over a period of time and to coordinate all the care that the patient receives.

Secondary care is an intermediate level of health care that includes diagnosis and treatment, performed in a hospital with specialized equipment and laboratory facilities.

discussion I will divide this section into two points: the objectives and rationales discourse, and scholars' debates around decentralisation or recentralisation moves.

### **2.3.1 Objectives and rationales for the decentralisation of health systems**

Rationales for decentralisation of health systems often echo more general arguments in and around public administration related to allocative efficiency, empowerment of local governments, accountability and equity. But, as Bremner (2011) observes, advocates of health sector decentralisation tend to present three additional objectives: improving technical efficiency; enhancing the quality of health services; and stimulating innovation in service delivery. In terms of greater technical efficiency, decentralisation is often justified with reference to fewer levels of bureaucracy, greater cost consciousness at local level and the market discipline that seems to arise from the separation of purchaser and provider functions. In a second regard, the author argues, increase in the quality of health services is assumed to result from the integration of health services, improved information systems and better access to health care services for vulnerable groups. And in a third respect, the posited improvement in the innovation of service delivery is linked to the experimentation and adaptation that will supposedly arise from the increased autonomy of local government and institutions. These three factors tend to be the focus of critical appraisals of decentralisation in health systems (Atkinson, 2007; Bankauskaite and Saltman, 2007:16). Bankauskaite and Saltman (2007:16) argue that improvement in technical efficiency may require certain contextual conditions like incentives for managers, and warn that market-type relations may lead to some negative outcomes. When it comes to innovation of service delivery, the authors argue that it could increase inequalities. At this point is important to remark that technical efficiency and innovation are in close relation to the themes I explored in my work. As I will discuss in Chapter Four and Five, my interviews suggest that the issues pointed out by Bankauskaite and Saltman are applicable to decentralisation of pharmaceutical assistance in Brazil. Before I give more details of the Brazilian case, it is important to discuss how associated debates have played out.

### **2.3.2 Debates about decentralisation and recentralisation**

Decentralisation was initially cast as a solution to many problems faced by health systems – but complexity and issues around its implementation soon clouded the waters in this respect (Vrangbaek, 2007; Mosca, 2006). As a consequence, the appropriateness of these shifts of power between tiers of the state continues to generate significant debate (Peckham *et al.*, 2008). In particular, the posited benefits of decentralisation – such as tailor-made policies, service delivery supported by greater knowledge of local circumstances provided by local actors and locative efficiency of public goods and services – have generated ongoing debates (De Vries, 2000). In the

view of De Vries (2000), tailor-made policies that are responsive to local needs have, for example, been implicated in enhanced geographical inequalities in access to services. Moreover, allocation of resources according to local preferences and needs is under dispute since it can result in inequalities, considering the variation in the delivery of services or public goods between municipalities. De Vries states that it has also been suggested that officials most able to accurately gauge and respond to local circumstances are more likely to work at a national rather than local level.

In fact, De Vries (2000) argues that neither the arguments in favour of decentralisation, nor those in favour of centralisation, are convincing. The author argues that decentralisation and (re)centralisation “seem to be ongoing cycles in which trends and taking sides in the discussion succeed one another continuously” (De Vries, 2000:194). In terms of specific case studies Peckham et al. (2008:572), analysing the decentralisation of health services in the United Kingdom, argue that “policies are both centralist and decentralist at any time and at any level”. Similarly, health policy in the UK has been described “as a paradox of simultaneous centralisation and decentralisation” (Greer, 2011). Although the UK health system was decentralised after the creation, in 1998, of the devolved governments for Northern Ireland, Scotland and Wales, there are increased demands therein for greater central control in the name of cost containment, access, and quality improvement.

Similarly, the Spanish health system was transformed from a highly centralised regime to a democratic, highly decentralised structure. But it has been argued that decentralisation does not extend beyond the regional level and that some regional tiers have in fact assumed roles originally devolved to municipalities. Moreover, it has been suggested that in fact within some regions have recentralised powers originally devolved to the local level (Duran, 2011). This particular pattern of regional decentralisation is blamed for the often strained relationship between regional administrations and the medical profession, difficulties in coordination, financial problems and a failure to reduce per capita geographical inequalities in expenditure (Duran, 2011). Again, it is important to note that the same kinds of difficulties were found in the decentralisation of pharmaceutical assistance in Brazil, as I discuss in Chapter Four. Returning to the Spanish case, despite the difficulties indicated, Duran (2011) acknowledges that there is some consensus that decentralisation has stimulated investment in health care, advanced innovation in the delivery of health services and promoted initiatives shaped by local preferences. Such advantages attributed to decentralisation can be applicable to the Brazilian case, as I discuss in Chapter Six.

Norway provides another good example of the reversed approach to decentralisation of the health system compared to other European countries (Saltman, 2008). The Norwegian health system is characterised by a focus on equity, decentralised political governance and public ownership and control. But from 2002 the central government took responsibility for all public hospitals. Hospital management responsibilities were recentralised from 19 counties back to five regional health authorities. Driving forces toward these reforms have been the lack of “geographical equity” and a desire to end the “economic blame game” between local and central government.<sup>28</sup> Reforms seek to resolve long waiting lists for elective treatment; lack of equity in supply of hospital services; and lack of financial responsibility and transparency (Saltman, Bankauskaite and Vrangbaek, 2007:228). Magnussen (2011) argues that it was a response to the practice of hospitals in deficit requesting help from sub-regional counties (who had no discretion with regard to setting taxes) that, in turn, would seek assistance from the central government. But the distribution of specific funds to the five regional health authorities quickly became a political issue and it was not until 2009 that agreement on related mechanisms for fund raising and redistribution was reached. Even after this reform, however, four of the five regional health authorities were in substantial deficits – a factor in sparking debates over structural reform (Magnussen, 2011).

From the examples discussed here, it can be seen that scholars have identified significant tensions between the impetus towards decentralisation and recentralisation in health policies. Debates about the suitability, degree and functions to be decentralised vary markedly within and between health systems. The adequacy of decentralisation is under question in European countries that are, in some cases (including Norway’s), reversing the trend and beginning to recentralise some functions within their health systems (Saltman, Bankauskaite and Vrangbaek, 2007).

As seen from the debates highlighted in this section, the decentralisation process distributes power to subnational levels, brings new actors to new political arenas and provides a formal opportunity for public participation in health policy-making process. To help unpack such complex and multilayered relations, the theoretical and analytical aspects related to these new arrangements and the relative power and influence of the stakeholders are reviewed in the next section.

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<sup>28</sup> “Economic blame game” refers to the struggle between county councils and central government in which both levels tried to pin responsibilities on the other for the sector’s inability to attain goals such as reduced waiting time for elective patients, higher cost efficiency and cost control.

## **2.4 Theoretical and analytical aspects of power and policy change**

While the preceding sections encapsulated contributions in the literature on definitions of decentralisation; academic perspectives on decentralisation at a general level; and associated analyses that focus upon health services, at this point it is important to introduce some concepts related to power and policy change.

### **2.4.1 Approaches to understanding the policy-making process**

Until recent decades the analysis of health policy tended to focus upon a restricted range of actors – ‘the state’, politicians, bureaucrats and fairly clearly defined interest groups (Walt *et al.* 2008). In the last decade, health policy and the policy-making have changed to incorporate more players (Buse, Mays and Walt, 2005). Notably, public-private partnerships have become a feature of many health systems. Traditional distinctions between top-down and bottom-up policy formulation and implementation have become less clear-cut in many instances – we have seen the evolution of policy networks or even policy “communities” (Tantivess and Walt, 2008). Moreover, it has been suggested that it is often unrealistic to separate an appreciation of political calculation and strategies from understandings of how health policy evolves and is implemented. Buse *et al.* (2005:7) emphasise this point, stating that “the content is not separate from the politics of policy-making”. Against this background, again adopting the ‘realist’ approach commended by Pawson *et al.* (2005), which I discussed in section 2.1, I examine some of the ideas and perspectives on how to explore power in the context of the policy-making process of most immediate relevance to the research described in this thesis.

#### **2.4.1.1. Stage theories**

Stage theories break the public policy process into functionally and temporally distinct stages. The stages usually encompass agenda setting, policy formulation, policy implementation and policy evaluation. Discussion centres on the factors that influence processes within and between each stage (Walt *et al.*, 2008; Sabatier, 2007:6; Lee, Estes and Rodriguez, 2003:135). From the late 1980s onwards, the stages model began to encounter increasing criticism (Sabatier 2007:7). Criticism specifically targeted the assumption of linearity in the policy process; the delimitation of stages that are often not so clear-cut in reality; the absence of causal theory and the under-estimation of organisational complexity in modern governance (Walt *et al.*, 2008; Sabatier, 2007:7; Lee, Estes and Rodriguez, 2003:139). Some of the alternative approaches that attempt to engage with such complexity are discussed below.

#### **2.4.1.2. Institutional approaches**

Institutional rational choice is a term that encompasses a variety of frameworks that centre attention on how institutional rules modify the behaviour of intentionally rational individuals motivated by forms of self-interest (Sabatier, 2007:8). In one variant, Institutional Analysis Development - most closely associated with Ostrom (1998) - stresses the role of self-interest but acknowledges that rational choice cannot be applied to all cases and contexts. Ostrom analysed how groups of people can exploit natural resources in a sustainable manner, even without government regulation. Regarding environmental protection initiatives, she proposed a polycentric approach where management decisions should be made close to the place where actions take place by the actors involved (Tucker, 2013). Ostrom's approach is to rethink the institutional theories and problems of governance in light of lessons learned from public-choice. She attempts to replace the state-centred view with a pluralist and polycentric one, where power is seen as something that is widely distributed in society. Ostrom's work challenges the monocentric vision and the existence of a unique centre of power and authority centred in 'the state' and shows that 'seeing like a state' is not inevitable when thinking about collective-action problems and solutions (Tucker, 2013). Ostrom's work on governance contributed to the transition from public choice to the new institutionalism, which encompasses the logic of institutional diversity, social heterogeneity and value pluralism. Moreover, Ostrom recognises the importance of institutions in policy outcomes, but challenges centralisation and monocentrism as key principles of governance. The application of institutional approaches tends to be more convincing when the preferences of actors are clear and stable but is unable to explain where those preferences come from and why they change (John, 2003).

#### **2.4.1.3. Multiple-streams**

This model of policy-making, often associated with Kingdon's model of agenda-setting (1984), focuses on the flow and timing of policy action and is useful in understanding the complexities and realities of policy-making. In this model three streams of actors and processes contribute to the policy formulation and implementation. These are the problem stream (or problem recognition with regard to potential policy interventions); the policy stream (concerned with formulating policy in relation to perceived problems) and the political stream (consisting of various elements such as public opinion, political parties, political debate, pressure group activities and government prioritisation of legislative issues) (Sabatier, 2007:66). Kingdon (1984:119) explains that for an issue to become a policy problem, people need to be convinced that something should be done – the issue has to enter the recognised problem stream if it is to receive the attention of government. The author argues that there are three mechanisms to draw government attention to problems. These are indicators (measurements used to assess the changing scale and import of problems);

events (disasters or personal experiences which focus attention on problems) and feedback (information on current performance that shows either a failure to meet objectives or unexpected consequences). And at critical times the problem, policy and political streams come together. “A problem is recognised, a solution is developed and available in the policy community, a political change makes the right time for policy change, and potential constraints are not severe” Kingdon (1984:174). These streams move independently through the policy system according to their own logic, until a window of opportunity is opened and two or more streams coincide and “become” a policy issue. This streams model, unlike stage theories, does not picture the policy-making process as linear and based upon discrete stages. Instead, the policy process is seen to be shaped by the intersection of at least two independent streams at one time. The model also acknowledges the multiplicity and unpredictability of diverse policy actors.

#### **2.4.1.4. Punctuated-equilibrium framework**

This framework was originally developed to integrate the literature on policy incrementalism and agenda-setting.

Incrementalism was proposed in 1959 by Lindblom as an alternative to ‘synoptic’ models of decision-making (Allison and San-Martin 2011; Atkinson 2011). According to the incrementalism concept “decision making is, and ought to take place through, a process of successive limited comparison”(Allison and San-Martin 2011:1).<sup>29</sup> Agenda-setting is the process by which issues enter the policy agenda. Models of agenda-setting focus on the mechanisms that explain how an issue is chosen by policy makers from a large number of issues that all potentially worth attention of the government. According to Buse *et al.* (2005:67) there are two prominent models of agenda-setting: Hall’s and Kingdon’s models. Hall’s model proposes that whether or not a particular issue will reach the government agenda depends on legitimacy, feasibility and support levels.<sup>30</sup> Kingdon’s model is explored in this section in the multiple streams framework (see below).

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<sup>29</sup> There is a distinction between incrementalism as an approach to policy analysis on the one hand, and a pattern of policy change on the other (Allison and Saint-Martin 2011). In the case of the punctuated equilibrium framework, the policy analysis dimension was used.

<sup>30</sup> Legitimacy is an attribute of a particular topic with which governments consider they should be concerned and in which they have a right or obligation to intervene. It refers to issues that are in the domain of government regulation. Feasibility is concerned with the potential for implementing the policy and depends on workforce and technological and financial resources. Support is related to the public support to the government regarding the subject of the policy (Buse *et al.* 2005:68).

Punctuated-equilibrium framework is based on a view that the policy process is characterised by long periods of stability interspersed by brief periods of instability and major policy change. The model of policy change proposed by Baumgartner and Jones (1993) argues that a so-called ‘punctuated equilibrium’ is underpinned by two forces - policy image (how issues are portrayed) and institutional policy venues (the institutional context of issues). The scholars argue that incremental policy change is often due to constraints on individual decision-makers. In broad terms these constraints include institutional cultures and accepted practice, the influence of powerful vested interests and bounded rationality<sup>31</sup>. Periods of stability are characterised by agreement around how issues are portrayed on the policy-making agenda. Modifications of some conditions, especially in society (such as public opinion and media attention) or government (such as significant electoral change) allow issues to emerge and, potentially, to bring about change in previously stable institutional arrangements (Parsons, 1995:204; Baumgartner and Jones, 1993:20). As Baumgartner and Jones (1993:20) put it: “Each time there is a surge of media interest in a given topic we can expect some degree of policy change”.

#### **2.4.1.5. Advocacy coalition frameworks**

Advocacy coalition frameworks synthesise elements from top-down and bottom-up perspectives within the policy implementation literature (Sabatier, 1997:292). The approach views the policy process as a competition between alliances of actors who advocate beliefs about policy problems and solutions. Sets of actors compete for influence over government agencies to advance their policy objectives (Sabatier, 1988). This framework fuses elements from top-down and bottom-up approaches. In bottom-up terms a variety of public and private actors are seen to participate with regard to aspects of policy formulation and implementation. And in top-down terms the framework addresses the reality of socio-economic conditions, legal systems and political processes in constraining behaviour. Significant policy change can thus often be linked to two circumstances - fundamental change in the external environment (such as a change of government) or significant change in ordinary conditions as a result of learning processes and interactions between advocacy coalitions within the specific policy communities. Kubler (2001), for example, uses the advocacy coalition approach to argue that a harm reduction policy adopted as a result of the arrival of the AIDS epidemic could be explained in part by a coalition of AIDS policy actors who succeeded in displacing a previously dominant coalition that advocated sexual abstinence.

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<sup>31</sup> The term ‘bounded rationality’ was coined in 1956 by Herbert Simon and the idea is that human beings are limited in their capacity to process information. Individuals endeavour to be rational, having first simplified the choices available; consequently, the decision-maker chooses between reduced options (Simon, 1976).

#### 2.4.1.6. Policy networks

The policy network concept arose from the idea that the government was not the only actor ‘in command’ of society, and that policy-making actually resulted from the interplay of various actors (Klijn and Koppenjan, 2000). The network framework emerged from organizational sociology and posits that the structure of coalitions across complex policy sectors determines the policy outcome (John, 2003). There may exist bargaining and negotiation at a variety of spatial levels such as those of central, regional and local state organisations together with the private sector. These levels may be dissected by a variety of institutional or informal linkages between major interest groups - a system of “policy networks”. There may, as has been intimated, be institutional or legal imbalances in power between groups, but the manner in which protagonists select and deploy resources and plan strategies is highly variable. A critical distinction thus exists between structurally imbued potential power and strategically realised effective power. There is no inherent reason why actors/groups should exhibit similar strategies or foresight in exploiting potential power. Indeed, there may be considerable scope for actors/groups to develop and exploit “informal” rules of negotiation and conflict and exchange resources with other interests to their own benefit. Hardy *et al.* (1990:143) produced a study of policy network related to the implementation of a community health policy, which suggests that “[a]n organisation which effectively deploys its resources will maximise its scope for decisional manoeuvre (or discretion) and be able to choose among various courses of action or inaction”. More specifically, Lewis (2005:170) characterises the health system as a network of interactions between people, organisations, structure and ideas. She proposes that a framework for analysing health policy should thus be based on the concepts of networks, ideas and power. She argues that each of these themes is essential to deal with a particular aspect of health policy. Networks reflect connections and relationships in the health policy process. Ideas are indicative of contested or uncontested foundational paradigms and the discourse around problems and solutions (such as the preventative model in health care). And *power* centres on the politics pertaining to the distribution of resources and influence.

As explained by Rhodes (2006:425), “a policy network is one of a cluster of concepts focusing on government links with, and dependence on, other state and societal actors”. The policy network approach is diverse and widespread in social science disciplines. It ranges from social network analysis to policy network analysis, including network society approaches and cross-cultural analysis. Policy networks, for instance, were used to describe government policy-making on Australia, Canada, UK and USA (Rhodes, 2006). As Rhodes (2006) argues, the policy network approach in itself has a broad and diverse scope. In this section I just introduced some elements relevant to my subject, namely those related to the notion of negotiation of various actors at different levels and inherent imbalances in power involved in policy processes.

#### **2.4.1.7. Policy triangle framework**

The policy triangle framework, developed specifically for health policy analysis, considers the content of policy, but also acknowledges the central role of the actors involved, as well as the context and the process (Walt and Gilson, 1994). This framework reflects how the interplay of these elements affects the policy-making process. ‘Content’ reflects the subjects and topics covered by a specific policy. “Process is concerned with the way in which policies are initiated, developed, implemented and evaluated. Actors – individuals, groups or organisations - are central to the framework” (Buse, Mays and Walt, 2005:9). Such groups, within and beyond formal institutional apparatus, may either seek to exercise power or simply influence the nature of policy. Finally, the ‘context’ is related to the general factors in the economic, political and social spheres that may influence health policy. Those contextual factors are categorised by Leichter (1979:41) as: *situational factors*: temporary conditions - such as wars, flooding or the HIV/AIDS epidemic – that may influence policy; *structural factors*: the relatively stable characteristics of society that may include the political system, the economy and demographic structure, technological advances and national wealth; *cultural factors*: such as religion; gender roles; the position of ethnic minorities; linguistic differences; social hierarchies and the size, quality and organisation of a civil service; and *environmental or exogenous factors*: mainly associated with the international environment. Some health issues require cooperation between national and transnational organisations, and those interactions generate interdependence between states as a result of agreements and financial obligations.

#### **2.4.1.8. Interpretative policy analysis**

The emergence of interpretative approaches in social sciences, in the late 20<sup>th</sup> century, has its roots on the broad intellectual movement contesting the dominance of positivist science and empiricist research enquiry. When it comes to doing interpretative policy analysis, there is a variety of methodological approaches “ranging from finding meaning behind a particular policy, to reconstructing the genealogy of a social institution, engaging in critical discourse analysis, sustaining a policy mediation effort, and to large scale action research on pressing social problems” (Wagenaar, 2011:241).

Wagenaar (2011) offers a comprehensive review of the literature on interpretative policy analysis field. His book provides an insightful ordering of meaning, which cut across the myriad of interpretative approaches in the literature. Differences in ontological and epistemological

assumptions informed the ordering adopted by Wagenaar in his book. The three types of meanings proposed are: hermeneutic, discursive, and dialogical. As he explains, they are not hardwired categories but rather represent the predominant interpretative framework applied by the analyst to capture meaning. Wagenaar affirms that in interpretative analysis, usually, the analyst employs one of the three approaches to explore meaning. Each of the three approaches revolves around different questions, and consequently generates different types of analysis leading to different conclusions. First, hermeneutic meaning considers the common intelligible context, which Wagenaar refers to as the background of common understanding. When s/he adopts this tradition the researcher interprets the actions of the individual taking into account the background of common understanding. The second type, the discursive meaning, relates to linguistic-practical frameworks that shape our comprehension of everyday practices as natural and self-evident or bizarre and illegitimate. The aim of the researcher, in this case, is to evidence from where these interpretations of practices emerged, and how it forces some individuals' practices and permit others. The third type, dialogical meaning, relates to social and practical nature of meaning. Individual agents' self-understanding (and understanding by others) is linked to social interactions in a 'taken for granted' world. In this tradition, the focus of the researcher is on how meaning is constructed as a result of social interactions in everyday situations.

In short, the different approaches to understanding the policy-making process discussed in section 4.1 consider how, to various extents, the political, economic and social factors may influence the way policies are developed and implemented. The combination of these factors provides the context within which health policy is constructed.

#### **2.4.2 Conceptualising power in the policy process**

The idea of power is central to understanding the influence of diverse actors in the policy process (Buse, Mays and Walt, 2005:10). Several theories help to understand the relationship between power and policy-making. Seminally, Lukes (1974:25) – in criticising the views of power proposed by American pluralists - outlined a three-dimensional view that incorporates the less visible dimensions of power and attendant relationships. As Buse *et al.* (2005:21-23) observe, Lukes conceives three types of power or, rather, three faces of power:

*Power as decision-making:* this focuses on individuals and groups that participate in or influence directly policy decisions;

*Power as a non-decision making:* this focuses on how powerful groups limit the scope of the policy agenda and thus prevent active and open

discussion of some issues. Crimson (1971), for example, sought to discover why air pollution remained a “non-issue” in many American cities. Findings tended to confirm the discursive circumscription described by Lukes;

*Power as thought control:* this focuses on the ability to influence others by shaping their preferences. This may be accomplished through subtle means to change meanings and perceptions of reality.

Foucault’s conception of power provides what is called ‘the fourth face of power’ (Digeser, 1992). The fourth face of power, unlike the other three faces discussed, is not restricted to coercive or repressive power to force individuals to do things. As Digeser’s seminal work on the fourth face of power showed, the Foucauldian notion of power is linked to a productive force: power produces subjects<sup>32</sup>. Besides producing reality, power is present in all social practices, and mediates all human relationships.

Another important aspect in Foucault’s conception of power is disciplinary power, which is exercised, via dominating narratives, by the creation of norms of what is acceptable. Those who fail to follow the norms governing our self-understanding and political practices face social pressure to conform. Digeser argues that the general concept of disciplinary power is still relevant for policy enquiry even to those that do not agree with Foucault’s claims. Digeser (1992:980) summarises sharply the differences in the kind of enquiry entailed by each conception of power:

*Under the first face of power the central question is, "Who, if anyone, is exercising power?" Under the second face, "What issues have been mobilized off the agenda and by whom?" Under the radical conception, "Whose objective interests are being harmed?" Under the fourth face of power the critical issue is, "What kind of subject is being produced?"*

But, for our purposes, the main disjuncture at a meta-theoretical level with regard to power is between pluralists who see power as fragmented and distributed to more or less equal degrees (according to the context and issue) and a variety of other perspectives that regard power as

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<sup>32</sup> Digeser (1992:980) states that “[s]ubjects are understood [by Foucault, in the fourth face of power] as social constructions, whose formation can be historically described. Foucault’s use of the term power is part of his description of this formation”.

concentrated among small elite groups (Hill, 2005:50). Drawing on the works of Buse *et al.* (2005:26-36), Hill (2005:25-62) and Parsons (1995:248-270) I outline the main perspectives:

*Pluralist perspectives* – in extreme forms – argue that power is spread throughout society and that the state, in the interests of what is best for society, assumes a position of neutrality to decide between conflicting interests in relation to the development of policy. From this perspective health policy is shaped by disputes and debates by different interests that are resolved, on an ongoing basis, by an impartial state in the interest of the greater good. Proponents of the pluralist approach thus usually consider interest groups as important conduits between the people and government (Walt, 1994:97). In this idealised model sensible policies would always take priority, although some interest groups do - in reality – subordinate the greatest good to their own interests.

*Public choice* theory, conversely, sees the state as encompassing specific interest groups. These include elected politicians but also government departments, civil servants and trade unions. In order, for example, to keep themselves in power and ensure re-election, elected officials reward key constituencies with enhanced public expenditure, particular services or favourable regimes of regulation and taxation. Similarly, civil servants may exploit their importance to political decision makers and those who rely on provided services to ensconce and bolster their own position.

*Elite perspectives* focus on the way in which power is concentrated. Theorists argue that the power to influence the policy process is often concentrated among privileged political, economic, social or professional groups. As a result, public policy may reflect the values and interests of these elites and not the interests of the broader public. Examples might include the influence wielded by the medical profession, the tobacco, alcohol and pharmaceutical industries.

*Marxist approaches* focus on class conflict and economic power. In this model, power is distributed among classes according to ownership and/or control of the dominant means through which capital is accumulated

(such as the manufacturing and service sector). The state relies on taxation generated by such capital to provide public services, and most workers have no option but to rely on paid employment. Moreover, increasingly over time, private capital can relocate to anywhere in the world, affecting nations' policy processes. Accordingly, those who own/control the means of accumulation exercise a disproportionate influence over economic parameters of policy, whether directly or indirectly.

*Corporatism* focuses on the power of organised interests – such as the state, trade unions and associations that represent the private sector - but with reference to their cooperation rather than competition. Such interests may come together to influence policy in fields such as health insurance and regulation of the medical profession to the exclusion of less organised and less powerful groups (such as those who depend on public welfare or patients).

*Professional influence* focuses on the power of professional elites who may prioritise their own interests over those in society for whose benefit they supposedly exist. According to Parsons (1995:263) “neo-elitist” perspectives have focused on these groups and have shown how they play a major role in the shaping and implementation of policy. For example, in a study of American health care, Alford (1977) argues that health professionals (doctors) and corporate rationalisers (managers, planners, administrators) exercise considerably more influence than the “repressed” interest of patients.

### **2.4.3. Models to equate the exercise of power**

Although scholars have offered several concepts to frame the study of power, how do we recognise and trace the exercise of power? One early response is reflected in Easton's (1965) model. This highlights the role of inputs, outputs, and the linkage between them (including a feedback loop) in the policy process. Inputs reflect the demands made by individuals or groups on decision makers and attendant levels of public support or opposition. Inputs feed into policy-making and may or may not, according to particular circumstances, help to shape outputs in the form of goods, services, legislation or taxation. The feedback loop refers to the manner in which outputs help to shape future inputs. The model is, however, very general and does not make clear exactly how inputs become outputs – decision-making within the government is thus still viewed as a “black

box” (Buse, Mays and Walt, 2005:34). Buse *et al.* (2005:34, p39) then outline three contrasting approaches to the decision-making processes within the black box – the rational, incremental and mixed perspectives, which I will now discuss.

#### **2.4.3.1. Rational models**

Simon (1976:62-78) developed a ‘rational’ model of decision-making in his work on how organisations make decisions. The author argues that the model of rational choice involves selecting the policy option that is most conducive to the achievement of organisational goals. It is necessary to follow a logical sequence of six steps to achieve such goals. The steps, briefly, are - 1) identify the problem to be solved and separate it from other problems, if possible; 2) clarify and rank the goals, values and objectives of decision makers; 3) list all alternative strategies for achieving their goals; 4) undertake a comprehensive analysis of all the consequences of each of the alternatives; 5) compare each alternative and its set of consequences with the other options; and 6) choose that alternative which maximises their values and preferences. A more recent but less prescriptive variant of this approach is stakeholder analysis. This approach also seeks to gather knowledge about actors, their behaviour, intentions, interrelations, interests and influences on decision-making or the implementation processes (Varvasovszky and Brugha, 2000). Reed (1999) defines stake as “an interest for which a valid normative claim can be advanced”. Carrying out a stakeholder analysis helps to build an understanding of the decision-making process within a given context. This broad perspective may be particularly useful where authority is shared among actors and institutions or where different policies are closely intertwined (Weible, 2007).

#### **2.4.3.2. Incremental models**

Proposed by Charles Lindblom in 1959, in this model, decision-makers take incremental steps, introducing small changes that may challenge the status quo only in a marginal way. Lindblom explains that in this model a good policy will secure the agreement of the various interests at stake. According to Lindblom, this model better describes the actual process of decision-making and incremental steps also allow inadequate decisions to be amended before the next step. Incremental strategy is seen as a more democratic approach than the centrally coordinated approaches provided by the rationalists. Path dependency and the inherent inertia of the institutions (mainly those set up by the government) have been used to explicate incremental changes (Falleti, 2010). If on the one hand the incremental model provides a more realistic account of the decision-making process than the rationalist models, on the other hand critics of incrementalism argue that the model is not able to explain radical changes. The model has been criticised for not handling what drives the incremental steps. An incremental model is likely to be unfair because it favours those with more

power. This conservative decision-making approach discourages decisions to introduce changes that run counter to the status quo and that would benefit the most needy.

#### **2.4.3.3. Mixed-scanning model**

Mixed approaches were proposed to address the criticism and limitations of both rationalist and incrementalist models. The idea was to combine the idealism of the rational approach with the realism of incremental models. This combination would overcome the unrealistic requirements of rationalism and the conservative approach of incrementalism. Etzioni (1967) proposed a mixed-scanning model of decision-making which combined a broad scan of the situation with a more detailed view of certain areas based on weather forecasting techniques. The author claimed that the mixed model was useful to the decision-making process and also provided a good description of the process in practice. Etzioni proposed a distinction between major and minor decisions. In his model major decisions required a broad analysis of the area without detailed examination of the policy options (as suggested by rationalists). Minor decisions (which follow up fundamental decisions) could have a more detailed review of the options. The broad overview would overcome the unrealistic expectation of rationalism by reducing the details required by major decisions, while helping to deal with the limitations of the conservative approach of incrementalism.

Buse *et al.* (2012:43) states that the mixed-scanning approach is used in some countries by Ministries of Health to estimate the overall burden of diseases which will inform the prioritisation of specific disease programmes and the correspondent resource allocation. The mixed-scanning model is also associated with global health policy. In response to the growing burden of non-communicable diseases the WHO carried out a broad scan and selected cancer, cardiovascular diseases, respiratory diseases and diabetes as top priorities. Specific strategies to address each of these diseases were then developed, assessing detailed options on diet, alcohol consumption, and tobacco control, inter alia.

This section has shown researchers' views on how to study the exercise of power and its influence on policy-making, its implementation and outcomes. I will now turn to the panorama of the access to medicines in Brazil, more specifically on essential medicines, which constitutes a crucial aspect of my thesis. This overview is important to set some parameters for the analysis of basic pharmaceutical assistance as well as helping in the interpretation of my findings. As would be expected, a comparison of access figures before and after decentralisation reforms would help to

elucidate which approach gives the best results. However, this proved to be unfeasible, considering the poor data available, as can be seen in the next section.

## **2.5 Access to essential medicines in Brazil**

This section provides an account of the state of affairs regarding the public provision of essential medicines and access in Brazil. The access to basic medicines is an important part of my research questions. In order to investigate if decentralisation had positive effects on access or otherwise I discuss some aspects related to the availability of medicines in the public sector. I summarise the data combined with the resources allocated and public expenditure in medicines available in the literature. My aim with this section is to establish the panorama of public provision of basic medicines in Brazilian municipalities, and the main trends related to the management of that provision. The issue of access pervades all discussions throughout my work (but particularly chapters six and seven), so the overview provided by this section is crucial to inform my analysis.

This assessment of public provision of medicines is composed of three subsections. A discussion of the availability of essential drugs and the difficulties in comparing different studies is presented in the first subsection. The following subsection focuses on public expenditure on medicines as well as policies and programmes involved. The last subsection then centres attention on the role of private expenditure on medicines, exploring the impact of such expenses on household income levels.

### **2.5.1 Availability of essential medicines**

The right to access to essential medicines is supported by international treaties as part of the fulfilment of the right to the highest attainable standard of health (United Nations, 2007; United Nations, 2000; United Nations, 1966). Brazil has come a long way in the progressive fulfilment of these rights. As discussed in Chapter One, the milestones in this process of incorporating the delivery of medicines by the health system were: *(i)* the establishment of CEME (Central of Medicines) in the 1970s focused on public drug provision to the lowest-income population as well as putting in place public plants and laboratories to produce medicines; *(ii)* adoption of RENAME (National Essential Medicines List) to inform the priority medicines to be supplied to SUS users; *(iii)* the National Constitution of 1988 and subsequent legislation which enshrined the right to medicines and assigned the responsibility for provision of these products to the public health system, and; *(iv)* the NMP (National Medicines Policy) launched in 1998, based on a decentralised

management model, formulated primarily for the purpose of ensuring free provision of essential drugs through the public health system. Adding to these initiatives and policies to improve public availability of medicines is the public production of medicines (Oliveira, Labra and Bermudez, 2006). Currently, expanding the access to medicine is a major goal of the Pharmaceutical Assistance Policy in Brazil within the NMP.

Although access to health care, including access to medicines, is a right guaranteed by the Constitution in Brazil, this provision by SUS is not always as extensive as it should be. In this context, population and household surveys can provide knowledge about the evolution on access, about the implementation of important social programmes and hence about the ability of the government to deliver on a key obligation. Despite the national and international advances made in recent years with regard to access, the availability of essential drugs in public primary care units has repeatedly shown insufficient levels of coverage. As a consequence, the Brazilian population does not have access to medicine consistently (see for example OPAS, 2005:26). Adding to these indicators of poor availability is the increasing number of court cases demanding essential medicines via judicial orders around the country (Sant'Ana *et al.*, 2011; Borges and Ugá, 2010; Ferraz, 2010; Pepe *et al.*, 2010).

An important landmark in the measurement of access was the WHO's model for worldwide monitoring and evaluation of the country's pharmaceutical situation. The model has three levels of evaluation (Paniz *et al.*, 2010).<sup>33</sup> The first and second level assessments were conducted in Brazil in 2003 and 2004 respectively (OPAS, 2005). With regard to the second level, which is related to the objective of this section, a set of indicators to evaluate national drug policies was developed by the WHO, resulting in three categories of indicators: *structural, process and outcome indicators* (Brudon, Rainhorn and Reich, 1999). *Outcome indicators* in particular are intended to measure the results achieved and the changes that can be attributed to the implementation of the national medicines policy. These *outcome indicators* selected by the WHO are devised to assess the effects of implementing the policy on aspects related to access (availability and affordability of essential drugs), quality and rational use. Access to medicines has at least four dimensions - physical availability, affordability, geographic accessibility, and acceptability (or satisfaction) (Center for Pharmaceutical Management, 2003). My research explores two of the of the *outcome indicators* proposed by the WHO to assess the effects of changes introduced by decentralisation on the drug

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<sup>33</sup> The first level concerns the organizational structure and process of the pharmaceutical sector. The second level uses indicators of access, quality and rational use of medicine in order to evaluate the National Medicine Policy. The third consists of studies that aim to describe specifically detailed aspects of the pharmaceutical sector's organization.

policy in Brazil: availability of essential drugs, free of charge, in the SUS public health facilities, and affordability mainly regarding user co-payment and household expenditures on medicines.

Notwithstanding the efforts on proposed indicators, measures of access are not fully standardised worldwide, impairing comparison between countries. Measures used by developed and developing countries can vary (Kruk and Freedman, 2008). It is not always possible to compare even regions within the same country. As a consequence, there is no unique operational definition to medicine access, and that evaluation, according to Paniz *et al.*(2010), is “a subject under conceptual and methodological development”. The Brazilian case is no exception, as national publications relating to access, besides being scarce, employ different methodologies, hampering comparability.

Access is frequently evaluated not considering consumption conditions, i.e. research does not distinguish free from out-of-pocket access (Bertoldi *et al.*, 2009; Carvalho *et al.*, 2005). These two consumption categories are very important elements in the analysis of pharmaceutical assistance policies, since affordability is an issue of concern regarding equality of access, which is a significant aspect considering the inequalities in Brazilian society. The comparison is also compromised as some studies evaluate availability of medicine only for specific health services (Pinto *et al.*, 2010; Guerra Jr *et al.*, 2004; Karnikowski *et al.*, 2004; Santos and Nitrini, 2004) while in others availability is restricted to generic drugs (Miranda *et al.*, 2009). Despite the methodological differences, population studies in Brazil report medicine availability ranging from 55% (Karnikowski *et al.*, 2004) to 96% (Bertoldi *et al.*, 2009) regardless of the source of medication (free of charge or out of pocket). This is a wide range but what it really means to SUS users in terms of access is more complex to equate, as I explain next.

Bearing in mind these difficulties in comparing data from different studies and their limitations, I summarised data from seventeen quantitative studies measuring medicine access in Brazil conducted between 1998 and 2009, and the analysis is presented next according to the corresponding geographical region where the data were collected.<sup>34</sup> The study design, sample and study level vary, as well as the region covered and the medicine access characterisation. Specific studies about medicine access for STD/AIDS, tuberculosis, Hansen’s disease, endemic disease control and high cost medicines were excluded because these are beyond the scope of my work. Among the selected studies, five are national, six are regional, and six municipal. The majority of

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<sup>34</sup> Brazil has 27 states grouped within five geographical regions: North, Northeast, Midwest, Southeast and South. Other details retrieved from the selected papers are found in Appendix 2.

studies, twelve out of seventeen, used the methodology proposed by the WHO and the remaining five employed instruments developed by the researchers.

As for the sample, only two are population-based studies; two evaluate the access within the population covered by the Basic Health Unit (UBS-*Unidade Básica de Saúde*); and the remaining thirteen investigate health services and health service users. In terms of evaluated medicines, six studies investigate all medicine types which should be dispensed by the health unit or health service investigated; five evaluate essential medicines; three included selected drugs within WHO global and regional core drugs; and the remaining three studies include only selected medicines prescribed for: *i*) hypertension and diabetes treatment; *ii*) hypertension, diabetes and mental health treatments; or *iii*) chronic diseases and palliative cancer treatment. Besides the variation in terms of medicines assessed within the studies, diabetes and hypertension drugs are included within each of the medicine groups investigated. The considerable variability of approaches and instruments among the studies analysed corroborates the idea that the area is still in the methodological development stage. At least in Brazil it is more evident. Next I divide the studies into two categories: broader coverage (national and regional studies) and limited coverage (studies in states or municipalities within the five Brazilian geographical regions).

### **2.5.1.1 Studies with broader geographical coverage**

The studies included in this category collected data from 1999 to 2007. Regardless of the study design and the instruments used, the works suggest a general improvement in public availability of essential medicines as time progressed. In 1999 the proportion of medicines available in public health services over five states of the federation was 52.8% out of 40 essential medicines investigated (Cosendey, 2000). This figure is similar to that estimated by Karnikowski *et al.* (2004). According to the authors, in 2002, the public availability of 61 essential drugs (included in the RENAME-National Essential Medicines List) was 55.4% in eleven metropolitan areas distributed in the five geographical regions of Brazil. The following year, research designed to investigate the use of medicines by the Brazilian population found that 87% of the participants had succeeded in obtaining all the prescribed medicines (Carvalho *et al.*, 2005).<sup>35</sup> Among the 13% who failed to obtain their medication 55% of the interviewees claimed that lack of money was the cause of the failure, emphasizing the importance of the free distribution of medicines. A national household survey conducted in 2004 coordinated by PAHO (Pan American Health Organization)

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<sup>35</sup> This cross-sectional study used data collected in 2003 from the Brazilian World Health Survey using an instrument designed by the WHO to evaluate health systems performance of the member countries adapted to Brazil.

and the Ministry of Health found, on average, 73% of availability of essential medicines in public health units, and 89% of availability in the private pharmacy network (OPAS, 2005:26). These figures show the better position of the private sector, but also suggest that even in private establishments patients had difficulty finding essential medicines. It is worth observing that, according to the study, only 65.7% of the prescribed drugs were in effect dispensed, and on average 84.1 days of drug shortage were observed among the public health units investigated. Comparability of these last two investigations, however, is impaired. Although both are national, population-based household surveys had data collected in consecutive years (2003 and 2004) they investigated different medicines and used different sources of medicines to estimate access. Carvalho (2005), for instance, did not evaluate the public availability of essential drugs. Therefore, each work has conceptual variations which affect conclusions about access level achieved.

The remaining two studies within this category investigated selected medicines for treatment of chronic diseases. The first, a household survey conducted in 2005 in 41 cities in Southern and Northeastern Brazil, whose sample included people living in the coverage areas for primary health care clinics, showed that access to continuous-use medicines was 81% in non-elderly adults and 87% in the elderly (Paniz *et al.*, 2008). The second was a study conducted in 2007 to examine the availability of medicines for hypertension and diabetes dispensed by the FPB (Popular Pharmacy Programme) in public and private-managed units (Pinto *et al.*, 2010). The work found around 100% availability for drugs to treat both diseases in the private sector. However, the same research showed poor availability in public health units. Availability fell to 23.3% for diabetes drugs and around 87% for hypertension.<sup>36</sup>

A report by the Office of the Comptroller General (CGU – *Controladoria Geral da União*)<sup>37</sup>, which collected data from 10% of Brazilian municipalities from 2004 to 2006 shows that 24% of the municipalities investigated failed in the public delivery of medicines (Vieira, 2008). The most frequent problems were: inventory tracking missing or deficient (81%); inadequate storage (47%); share of state resources missing or in disagreement (28 %); expired products (22%); share of municipality resource missing or in disagreement (20%); and failure to follow rules of acquisition (19%). These findings suggest a close relationship between the establishment of efficient

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<sup>36</sup> The implications of the PFP programme for the public delivery of essential medicines is discussed in more detail in Chapter Seven.

<sup>37</sup> The Office of the Comptroller General is the agency of the Federal Government in charge of assisting the President of the Republic in matters which, within all areas of the Executive Branch, are related to defending public assets and enhancing management transparency through internal control activities, public audits, corrective and disciplinary measures, corruption prevention and combat.

programming and control of inventory with availability of medicines. Vieira (2008) argues that the first two management factors listed by the CGU report are the most important and would affect the efficiency of the pharmaceutical assistance programme more than the proper allocation of resources. The literature discussed in the section related to decentralisation factors cannot be dissociated from the context. Thus, assigning weighting factors based on their frequency alone might result in misleading conclusions. The failures most frequently reported are usually linked to low availability of medicines, but it is arguable to claim that one factor is more important than the other in causing the problem.

As gathered data suggest, there is currently insufficient evidence of improvement or not in public provision of medicines at the national level. Next I will show studies conducted in states or municipalities clustered according to region.

### **2.5.1.2 Studies with limited geographical coverage**

#### North and Northeast

The only existing data for these regions are part of national studies already discussed (Emmerick, Luiza and Pepe, 2009; OPAS, 2005; Cosendey, 2000). Regarding the northern states of Acre, Para and Amazonas, the studies report respectively 63%, 69% and 83% of prescribed drugs dispensed (Emmerick, Luiza and Pepe, 2009; Cosendey, 2000). Only for the states of Pernambuco and Sergipe, in the northeastern region, is there information available about access to medicines. A surprisingly high figure of 96% prescribed drugs being dispensed is described for Pernambuco, whereas Sergipe achieved only 55% (Emmerick, Luiza and Pepe, 2009; Cosendey, 2000). Although one could argue that Pernambuco has the best public provision of medicines within the northern and northeastern region and Amazonas in the northern region, these are only snapshots, having thus limited value and not supporting conclusive remarks.<sup>38</sup>

#### Midwest

Specifically for the Federal District, a study conducted in 2006 found that about 50% of patients did not receive at least one of the prescribed drugs (Siqueira and Gaulard, 2009). Shortage in medicine supply in the public health unit was reported, by 75.8% of the interviewees, as the most frequent reason for the failure in providing the full prescription. A propos of the ability of the health units to supply prescribed drugs, the percentage of medications dispensed in pharmacies of

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<sup>38</sup> These studies collect data once in each place using a small sample. These studies give results that can be both positive and negative and do not reflect the availability of drugs in the region during most of the year.

public health units was approximately 63%. Comparing with the 61.2% of drugs prescribed actually being dispensed, as obtained by Naves (2005) in 2001, this suggests that no significant improvement in the public delivery of medicines was made in the Federal District in the period analysed. In this particular case there are two consecutive studies in the same state which, to a certain extent, indicates that availability of drugs did not change between 2001 and 2006.

Data on access regarding Goiás state showed unpredicted results, considering the expectation of steady implementation of pharmaceutical assistance programmes by the government, suggesting inconsistency in the drug provision programmes. In 1999, a study which undertook analysis of the implementation of the Basic Pharmacy Programme found, within the essential medicines covered by the programme, 100% of the prescribed drugs were dispensed (Cosendey, 2000). Five years later, in 2004, Emmerick *et al.* (2009) found that no more than 74% of prescribed drugs were actually dispensed.

Thus, in two states of this region available data show no evidence of improvement in access.

### Southeast

Despite being the most populated and economically developed region in Brazil, Southeastern states also presented low levels of access to essential medicines in the few published studies for that region. A study which collected data from the public and private sector between 2000 and 2001 within two regions in Minas Gerais state reported 81% of availability of 21 indexed essential drugs in private pharmacies, whereas only 47% were available in public health units (Guerra Jr *et al.*, 2004). Two other municipal studies conducted in 1998 and 2002 within the Southeastern region reported around 60% of essential drugs prescribed being dispensed in public health units (Chaves *et al.*, 2005; Santos and Nitrini, 2004). More recently, a study conducted in 2006 in the municipality of Praia Grande in Sao Paulo state reported that the complete list of drugs prescribed for antenatal care was available in just 15% of the health services examined (Vieira, Lorandi and Bousquat, 2008).

Hence, data for the southeastern region show poor levels of availability of medicines in public services, and the values show discrepancy in relation to the national household survey conducted by PAHO and the Ministry of Health in 2004 (OPAS, 2005). Poor availability of medicines in this region, which in theory has the best infrastructure and economic resources in the country, could be interpreted as a failure in the decentralised model as it was implemented (Guerra Jr *et al.*, 2004).

## South

The most recent data about access to medicine in Brazil come from works conducted in the Southern region. A multi-centre study in six low and middle-income countries which included Brazil evaluated the public availability of 32 drugs used to treat chronic diseases (Mendis *et al.*, 2007). This study was conducted in 2005 in Rio Grande do Sul state in 20 public and 20 private health units and reported 30% public availability of drugs. Bertoldi *et al.* (2009) conducted a household survey in 2003 with subjects living in the Family Health Programme coverage area in Porto Alegre, capital of Rio Grande do Sul state. The study reports general availability of medicines of 96.4%. Although access in general was high, of all medicines used by patients, only 51% were obtained free of charge from SUS, whereas 41.5% were paid for out-of-pocket. The same study revealed that drugs used to treat chronic diseases had a higher public supply of 63%. Additionally, if only drugs to treat hypertension and diabetes were considered, the free supply covered about 80% of the drugs. This survey shows that almost half of the subjects who failed to use a needed medicine did not even search for them in SUS. A belief that the medicines would not be available in public facilities was given as one of the reasons for not searching. Considering the failures in the public provision of drugs already discussed, this low expectation regarding access to medicines in public facilities could be interpreted as a reflection of years of shortages in the availability of free medicines in Brazil.

The more recent accounts of public availability of medicines came from two other studies. The first is a multi-centre, longitudinal study which interviewed patients monthly in public health units from 2006 to 2008 (Dal Pizzol *et al.*, 2010). The study was carried out in eight municipalities in three states, and reported that 76% of all medicines prescribed were available free of charge. Higher public availability of 88% was reported if only essential medicines were considered. The second study collected data in six cities in the Southern region in 2008 and 2009 in public and private health units and pharmacies. The results compare well with previous studies, although they show a slightly lower overall availability of essential medicines of 69% in the public sector (Bertoldi *et al.*, 2010).

In summary, from the two groups of studies discussed here, one can conclude that access to medicines in Brazil improved. This conclusion, however, does not withstand closer analysis, especially with regard to public supply. Studies discussed here have shown that figures can vary substantially according to the region, and comparisons are fragile due to methodological inconsistency. From the literature gathered here it is reasonable to state that the big picture of

access to essential medicines is already to be done. The other side of this issue on access improvement is how much effort and resources the public sector is investing to improve the current situation. Pharmaceutical assistance programmes implemented by SUS are the main form of access to medicines, especially for lower-income population. The National Household Sample Survey in 2008 reported that among the population belonging to the bottom income deciles 48% of prescription drugs were obtained free of charge, whereas in the upper income levels this source represented only 10% (IBGE, 2010). The social importance of free provision of medicines especially amongst people from the lowest income strata was further strengthened by the results of a recent regional study, which showed the poorest decile of the population living in Porto Alegre relied on free medicines for 80% of their needs, compared with just 20% among those in the richest decile (Bertoldi *et al.*, 2011). The following subsection will further explore other factors that influence the public provision of medicines.

### **2.5.2 Public expenditure on medicines**

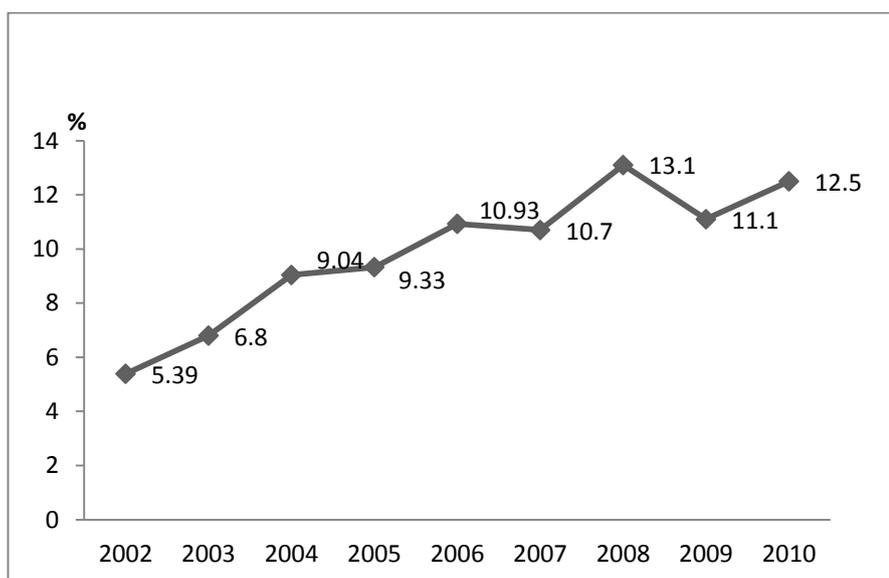
As introduced in the previous subsection, availability of medicines in the public sector still does not meet the challenge of supplying essential medicines to patients in need. This lack of access can result in failure to follow the recommended treatment, particularly amongst people in the lower socio-economic strata (Carvalho *et al.*, 2005). Public policies targeted to make essential medicine free of charge more widely available have been implemented over the last decade. The intensification in the efforts to provide access to medicine was indicated with the publication of the National Medicines Policy (NMP) in 1998 (Brasil, 2000). As a development of the NMP, several programmes were launched to guarantee access to medicine for the population. This led to increases in government spending on medicine, both in absolute terms and as a proportion of total health expenditure. The total spending on health (public and private expenditure)<sup>39</sup> in 2003 was 7.6% of the Brazilian gross domestic product, within which only 45.3% came from the public sector and the rest came from private expenditure. These figures are not compatible with the supposedly universal health system that Brazil has ‘on paper’, but in fact are comparable to those observed in other low- and middle-income countries where most pharmaceutical expenditure is privately financed (Lu *et al.*, 2011).

Between 2002 and 2007 significant growth in government expenditure on medicine was observed. In 2007 spending on drugs was 3.2 times higher, in absolute terms, than in 2002, accompanied by a rise from 5.4% to 10.7% in the proportion of expenditure on medicines related to the total

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<sup>39</sup> Private expenditure in this thesis refers to spending by citizens and families, as opposed to public expenditure, which refers to government spending.

government health expenditure over the same period (Vieira, 2009). The Ministry of Health's significant increase in total spending on drugs could be explained by the launch of the NMP in 1998, whose implementation either created or expanded programmes, aimed to guarantee the population's access to medicines as mentioned previously. As a result, a rapid growth in resource allocation for initiatives involving drug supply was achieved. The steady evolution of the share of expenditure on drugs in the National Health Fund (FNS)<sup>40</sup> total spending, as shown in figure 2.1, provides evidence of the importance attained by the programmes for provision of medicines throughout the years analysed.

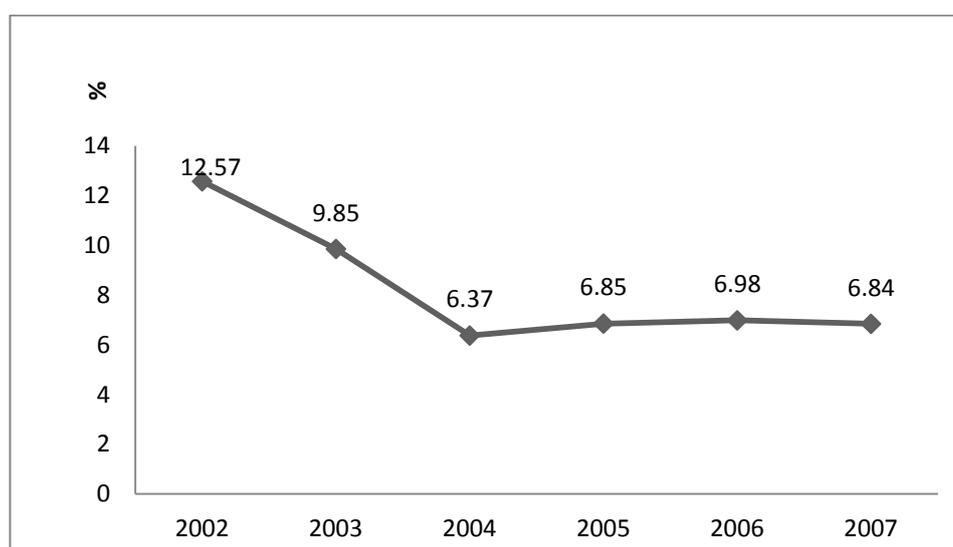


**Figure 2.1- Percentage of the budget of the National Health Fund allocated to purchase of medicines**

Sources: 2002 to 2007:Vieira (2009); 2008 and 2009: Ministério da Saúde/Secretaria de Ciência, Tecnologia e Insumos Estratégicos (SCTIE); to 2010: Brasil.CONASS (2010:14).

<sup>40</sup> The National Health Fund (FNS) is the financial manager at the federal level of the resources of SUS.

The preceding chart shows that the relative amount of the FNS allocated to drug purchase more than doubled in the last decade. Moreover, according to Vieira (2009), spending on primary care drugs increased, in absolute terms, by 75% between 2002 and 2007. However, as Figure 2.2 shows, the proportion spent on primary care drugs as a share of the total expenditure indicates an opposite trend. The percentage of the Fund assigned to the acquisition of primary care drugs was reduced from 12.57% in 2002 to 6.84% in 2007. A more detailed analysis of the data and context indicates that antiretroviral and exceptional circumstance drugs had a greater participation in the increased spending on drugs between 2002 and 2007. The fact that these drugs are under patent protection is indicated as a possible explanation for the large increase in spending.



**Figure 2.2- Percentage of the National Health Fund budget allocated to purchase of primary care drugs**

Source: Vieira (2009) and *Siga Brasil* System-Federal Senate<sup>41</sup>

The financing of public medicines delivery is fragmented into specific programmes resulting in complex mechanisms of resource allocation, which complicates the monitoring and analysis of public expenditure on drugs (Machado, 2007). It is worth noting that public pharmaceutical programmes are co-financed by the three SUS management levels: Federal (represented by the Ministry of Health), State, and Municipalities. The allocation of federal funds to finance the purchase of medicines is accomplished through a specific budgetary item named 'Bloco de

<sup>41</sup> Data available at : <http://www12.senado.gov.br/orcamento/tematicosaude> [last accessed in 17/06/2013]

Financiamento da Assistencia Farmaceutica' (or Pharmaceutical Assistance Funding Block), which has three components:<sup>42</sup> basic, strategic, and specialised component of pharmaceutical assistance. The Ministry of Health shares responsibility for the funding of basic and specialised components, along with the states and municipalities, and has exclusive responsibility for funding the strategic component. The following table shows the federal spending on drugs, according to two studies that have disputed views.

**Table 2.2. Federal medicines purchase spending in 2009 and 2010**

Year	Expenditure on medicines as share of total health expenditure (%)	
	Vieira 2009	Aurea <i>et al.</i> 2010
2002	5.39	-
2003	6.80	-
2004	9.04	-
2005	9.33	7.8 <sup>43</sup>
2006	10.93	5.9
2007	10.7	5.9
2008	-	5.48

Source: Elaborated by the author using data from Vieira (2009) and Aurea *et al.* (2010).

Although Vieira (2009) and Figure 2.1 suggest growth on drug spending, that analysis was challenged by the study conducted by Aurea *et al.* (2010) depicted in Table 2.2. This work

<sup>42</sup> Pharmaceutical Assistance Funding Block, which consists of three components: (i) Basic Component of Pharmaceutical Care funds the purchase of primary care drugs. Contributions for the funding are shared between Federal (50%), State (25%) and Municipal (25%); (ii) Strategic Component of Pharmaceutical Care funds the cost of drugs for the treatment of tuberculosis, leprosy, malaria, leishmaniasis, Chagas disease, and other endemic diseases of national or regional level, antiretroviral programme of STD/AIDS, blood components, immunobiologicals, drugs for giving up smoking, food and nutrition programmes and; (iii) Specialized Component funds high-cost medicines for diseases whose therapeutic approaches are established in Therapeutic Clinical Protocols and Guidelines (PCDT) which establish the medications available and who is responsible for their funding (state or federal level).

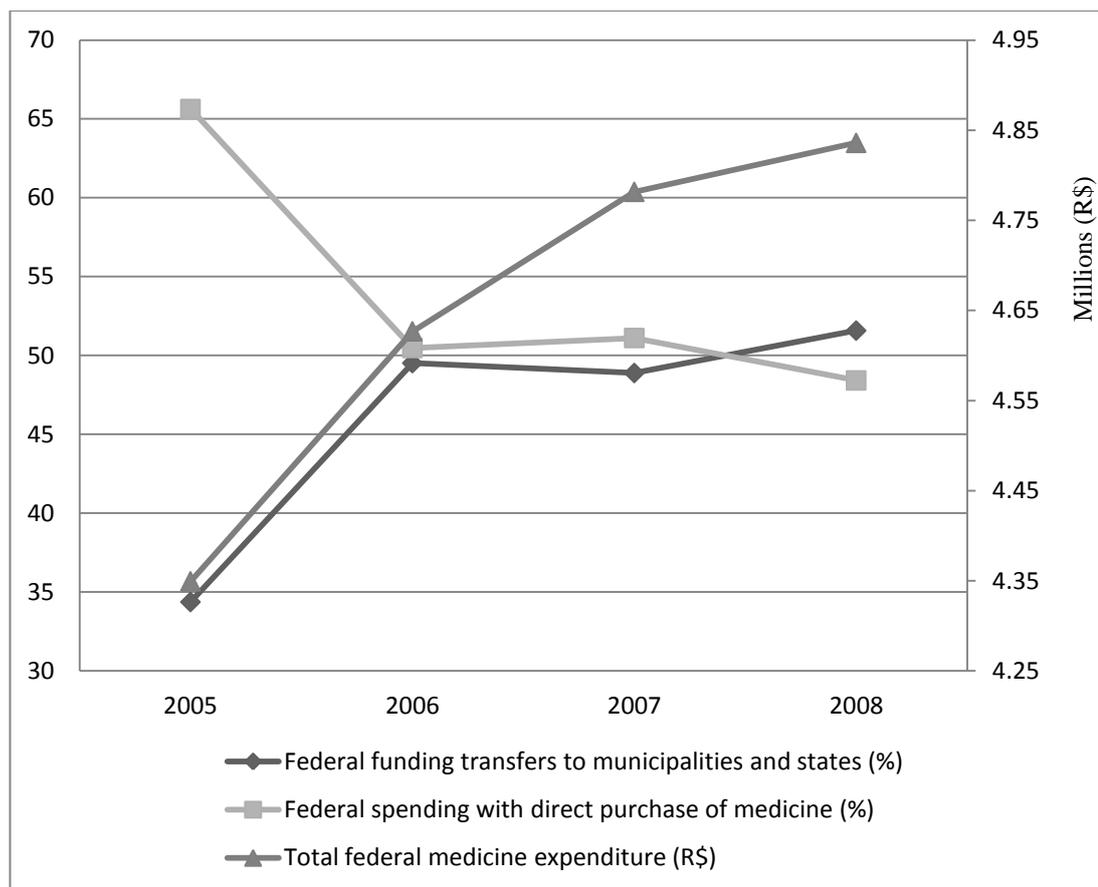
<sup>43</sup> A plausible explanation for this peak presented by the author could be a large amount of ARV drugs that the federal government purchased in 2005 compared to previous years, aiming to maintain adequate drug stocks during future price negotiations (Nunn *et al.*, 2007).

combined two national databases (SIASG<sup>44</sup> and SIOPS<sup>45</sup>) in order to analyse the spending of each of the three government levels. According to the authors, comparing the figures from 2005 to 2008, direct drug expenditure by the Ministry of Health was stable and even lower than in 2005 as shown in Table 2.2. The authors argued that studies using budget information, as Vieira (2009) did, could include other related expenditures than exclusively drug purchase, for example flight tickets or other daily allowances, payments to individuals (wages) or corporations depicting higher figures than the actual amount of money spent on medicines. In fact, when comparing 2005 and 2007, even Vieira (2009), who claims an increase in expenditure, shows an increment of only 1.4% in medicine expenditure. The next graph helps to understand why these expenditures are difficult to assess.

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<sup>44</sup> The purchase of drugs by the federal government is done through tenders and/or covenants. Purchases made through tenders are recorded in the Integrated General Services Administration (SIASG), which was one of the databases considered.

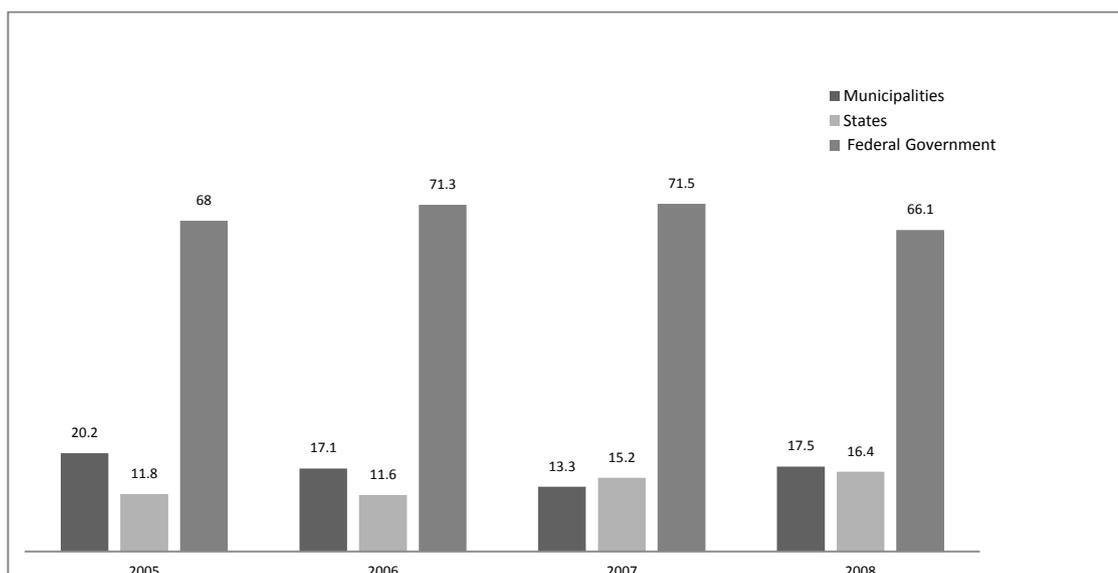
<sup>45</sup> To account for public spending on pharmaceutical assistance, the expenditure of states, Federal District and municipalities taken from the Information System on Public Health Budgets (SIOPS) was included.



**Figure 2.3 - Brazilian federal spending on medicines: direct purchase and federal funding transfers to states and municipalities, from 2005 to 2008.**

Source: Aurea *et al.* 2010, elaborated by the author

As Figure 2.3 indicates, the share of federal spending with direct purchase of medicines decreased in the period, while overall the federal funding transfers to states and municipalities for health have grown. However, federal funding transfers to subnational levels only showed growth from 2005 to 2006, and since then have remained stable. The drop in participation in the federal government's purchases of drugs could be explained by the decentralisation of pharmaceutical assistance, which led to the distribution of responsibilities and consequently to an increase in federal transfers to states and municipalities. The increase in transfers of funds was a development from the arrangement that distributed, to state and municipalities, powers and responsibilities in the acquisition and management of distribution of drugs. As I will further explore in Chapter Four, although the National Medicines Policy since 1998 foresaw the decentralisation of pharmaceutical assistance, it was only from 2005 with the enactment of the Statutory Order GM/MS n.1105/2005 that the process of decentralisation was actually initiated, leading to a consistent increase in the relative share of states and municipalities in the total public spending on drugs. Although decentralisation of pharmaceutical assistance was supposed to increase federal transfers, Figure 2.4 shows that the federal share varied little in the period analysed.



**Figure 2.4-Share of public expenditure on medicines (%) according to the government level, Brazil 2005 to 2008**

Source: Author using data from Aurea *et al.* (2010)

The increase in drug expenditure has been significant greater than the increase in health expenses. Vieira and Mendes (2007) considered the evolution of public expenditure on drugs over the period 2002 to 2006 and described a 124% increase in federal spending on drugs, while in the same period the increase in overall public spending on health was only 9.6%. A more detailed analysis showed that the main reason for the rise came from expenditure in the programme for provision of costly drugs<sup>46</sup> which presented an increase of 159%. In other words, the expenditure was 2.6 times higher in 2006 (increased from R\$<sup>47</sup> 516 million in 2002 to R\$ 1.3 billion in 2006), whereas growth in resource allocation to basic medicines was 62% comparing 2002 to 2006 - from R\$ 176 million to R\$285.6 million.

An analysis of the value disbursed by each of the three government levels in direct payment for medicines in 2009 showed a striking distribution if compared with previous years, as can be seen in Figure 2.4. The state level had the highest share of direct spending to buy drugs (47%) followed by the federal and municipal levels (about 26% each) (Vieira and Zucchi, 2011). This could be explained in at least two ways. First, states are concentrating purchases, and pharmaceutical

<sup>46</sup> Programa de Medicamentos de Dispensacao Excepcional or Componente Especializado, as it was named from 2009 (Brasil. Ministerio da Saude, 2009)

<sup>47</sup> R\$-Brazilian Real; currency; National currency units deflated using 2003 values currency calculated using the General Price Index DI elaborated by the Getulio Vargas Foundation.

assistance was centralised at the state level instead of municipal management, as would be expected with decentralisation. The second likely explanation is that the drugs whose purchase is under state responsibility saw their costs substantially increased, which led to a rise in drug spending. States are responsible for the purchase of medicines that are part of the specialized component (formerly high cost) and can also centralise the purchase of drugs from basic pharmaceutical assistance.

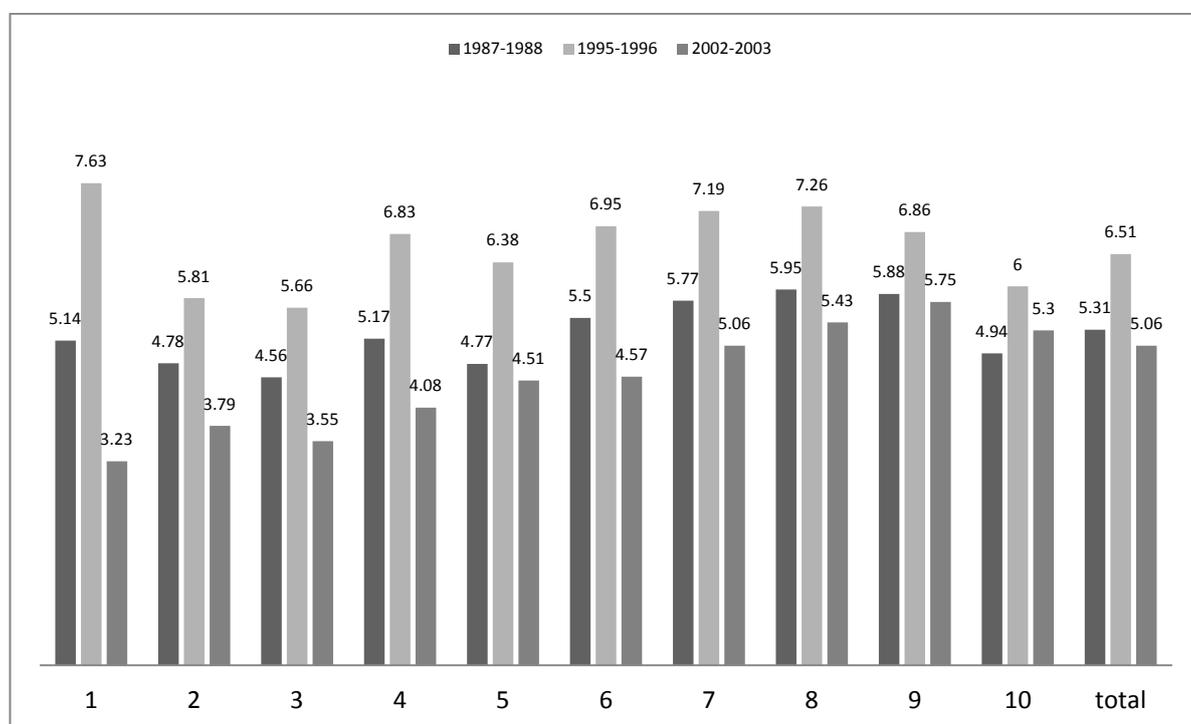
Unfortunately, Vieira and Zucchi (2011) did not collect data from the state of Parana. As I will explore in Chapter Six, this state implemented a consortium for drugs, which centralised purchasing at the state level; this consortium receives transfers related to the federal and municipal shares in the financing of basic medicines. Moreover, the authors observed an inverse relationship between *per capita* spending on medicines and municipal population. The mean *per capita* spending in municipalities with population below 5,001 residents was 3.9 times greater than in municipalities with a population above 500,000 residents. Differences in negotiating power and in the scale of purchases were indicated as a possible explanation for the difference in the *per capita* spending among different categories of municipalities. Another possible explanation not explored by the authors discussed in this review concerns the inefficiencies in the procurement process in small municipalities due to constraints on administrative resources.

At this point, it is important to remark on the distinction between free access and general availability in the Brazilian context. On the one hand, free access means that patients can obtain their medicines free of charge. Public provision is a responsibility of SUS as stated by law. On the other hand, general availability refers to all means to obtain the medicines regardless of the source, i.e. medicines can be obtained free of charge or paid out-of-pocket.

Although the preceding studies focused on drug spending, trying to correlate expenditure with implementation of health policies, the increase in public spending on medicines does not necessarily mean that it will be translated into increase in access. These two variables are not straightforwardly associated. In order to understand other factors that influence access, in the next subsection I will explore academic works dealing with private expenditure on medicines and what this represents for low-income patients.

### 2.5.3 Private expenditure on medicines

Among all health care expenses, purchase of medicines and payment of health insurance are the main household expenditures in Brazil. Medicines account for the largest share among the poorest members of the population (Silveira, Osório and Piola, 2002). National data on families' health expenditure in Brazil can be obtained through two types of household surveys, PNAD<sup>48</sup> and POF<sup>49</sup>, both conducted by the Brazilian Institute of Geography and Statistics (IBGE – *Instituto Brasileiro de Geografia e Estatística*). Studies using data from these databases indicate that the share of expenditures in health has been modified, mainly among people of the poorest income deciles. The following figure shows how these expenditures vary according to income level, as reported by Diniz *et al.* (2007).



**Figure 2.5 - Monthly health expenditure as share of family total expenditure according to income deciles (%)**

Source: Author, using and amending data from Diniz *et al.* (2007).

Figure 2.5 shows that, overall, while in 1987-1988 health accounted for 5.3% of total household expenses, the percentage increased to 6.5% in 1995-1996, and fell again to 5.1% in 2002-2003.

<sup>48</sup> PNAD- Pesquisa Nacional por Amostra de Município or National Household Sample Survey held annually across the country and which, in certain years, applies a supplement dedicated to health as occurred in 1998 and 2008.

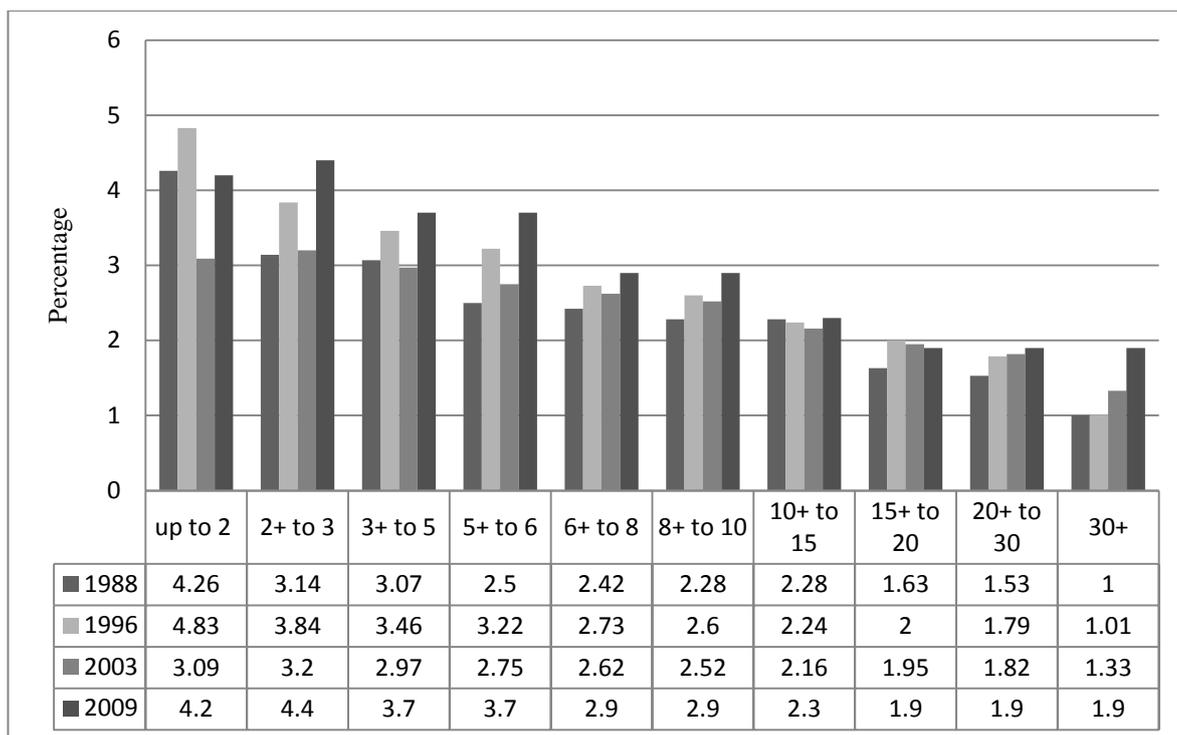
<sup>49</sup> POF – Pesquisa de Orcamentos Familiares or Household Budget Survey held every five years in specific metropolitan areas.

This trend for increased participation of health care expenditure between 1987-1988 and 1995-1996 and the subsequent drop in 2002-2003 took place in all income deciles. In the period between the first and second POF, the share of health spending has increased proportionally more for the poorest than for the richest population. However, data from 2002-2003 show that the share of health spending was reduced for all income deciles except for the richest. That is, for families in the lowest income bracket, the share of health spending in the household budget decreased from 7.6% to 3.2%, while for the top earners it decreased from 6.0% to 5.3% between 1995-1996 and 2002-2003. Diniz et al (2007) argue that the decrease in the relative share of health spending within total household expenditure observed in 2002-2003 could be attributed to a higher coverage by SUS, especially among the poorer segments of the population, as well as to the medicine provision policies implemented.

The information provided by POF and PNAD is not strictly comparable, not only due to differences in territorial coverage, but also to the instruments used. Silveira *et al.* (2002), however, argue that with regard to health spending, both surveys could be used in a comparative perspective since the overall picture outlined by the two surveys would be similar if certain measures were taken to match the data.<sup>50</sup> Combined data from POF-1995-1996 and PNAD-1998 revealed that spending on health accounted for 7% of the total disbursement of families every month. According to the study, this spending ranked fourth, coming after housing costs (29%), food (23%) and transportation (14%). Breaking down health spending, drugs accounted for 37% of these expenditures overall. Expenditures in the poorest deciles are qualitatively and quantitatively different from the richest deciles. According to POF 2008-2009 data, expenses with medicines by families in the upper income deciles accounted for more than nine times the expense of the poorest families. Although the families in the bottom income deciles spend much less on medicines (in absolute terms compared to wealthier families), they commit proportionately more income to the acquisition of medicines. I used data collected by IBGE to produce Figure 2.6 in order to show the profile of spending on medicine according to family income level across time. Comparing the share of drug spending in total household monthly expenses, the poorest households (those earning up to two minimum wages per month), as can be seen in Figure 2.6, represented 4.2% of its total expenditure monthly in 2009, whereas in the richest families this was only 1.9%.

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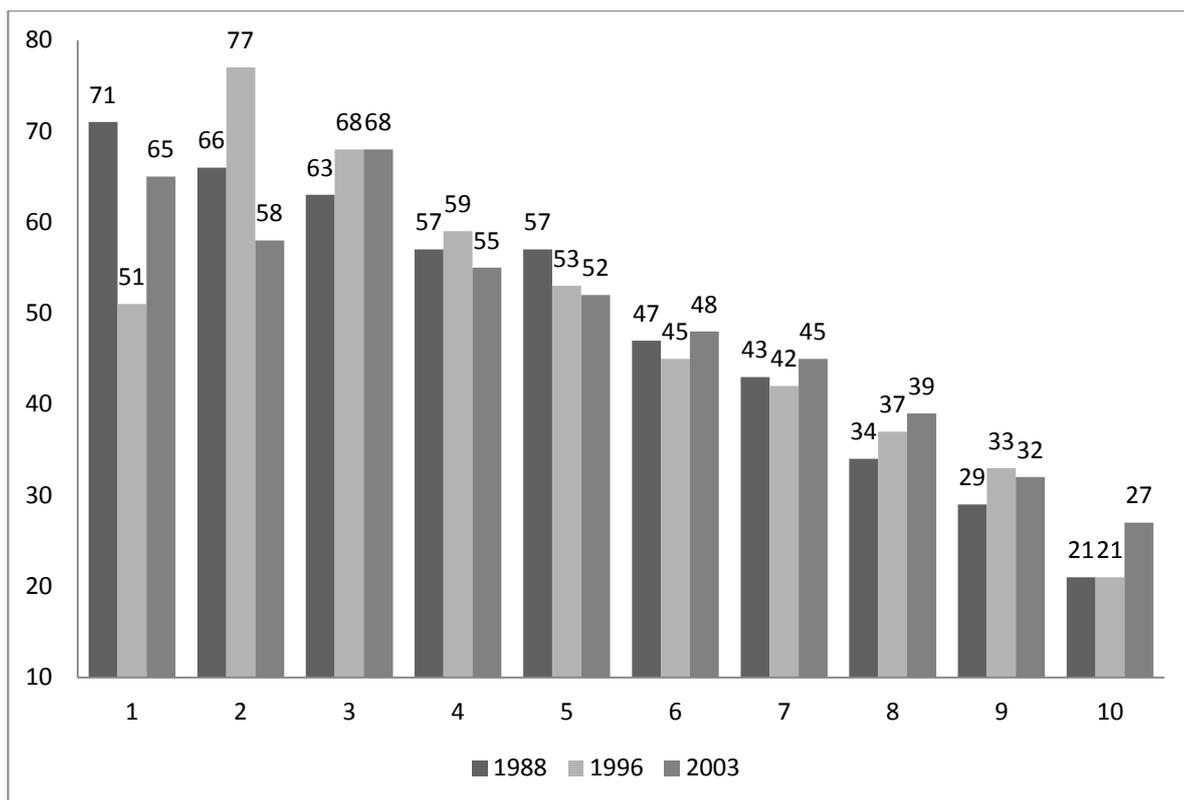
<sup>50</sup> The idea of reconciling data from different surveys in order to allow comparability was also embraced by Diniz *et al.* (2007) regarding POF data from three different periods which show variations in methodology and coverage.



**Figure 2.6- Expenditure on medicine as a share (%) of family monthly expenditure according to family income level in minimum wages**

Source: Author using data from IBGE /PNAD 1988, 1996, 2002, 2009

The uneven pattern of household spending on drugs, sorted by income level, has not changed substantially over recent years. As shown in Figure 2.7, data from POFs of 1987-1988, 1995-1996 and 2002-2003 present a tendency to maintain and even increase the difference in drug spending between the richest and the poorest families (Campolina et. al., 2007). While among the poorest the first category of health expenses is medicines, in the richest strata spending on private health insurance rose progressively. Still, drug expenditure represented a significant share of spending in all income deciles, and only among the 10 % richest strata was the share of health expenditures spent on health insurance higher than the fraction spent on medicines.



**Figure 2.7 - Expenditure on medicine as a share (%) of total health expenditure by families, according to income decile distribution**

Source: Author using data extracted from Diniz *et al.* (2007).

Regarding the expenditure on medicines, in recent years a range of studies has been dedicated to the subject. Barros and Bertoldi (2008), as already mentioned in the previous subsection, investigated a population living in the area covered by the PSF programme in the Porto Alegre metropolitan area, southern Brazil. The study was conducted in 2003 and reported that 10.5% of the total family income was spent on health and, within that, more than half (5.8 %) was spent on medicines. In other words, 55.2% of the total amount that families spent on health was on medicines. The share of health expenditure is higher than reported by national household surveys (see Figure 2.6) even if the poorest income level is considered. The results are remarkable considering that the population investigated lives in an area assisted by the Family Health Programme (PSF). Although 37.5% of the studied households came from the poorest deciles within the region, they lived in areas covered by the very PSF programme that was supposed to provide access to health care as well as to medicines.

Another cross-sectional population-based study carried out in 2009 in Southern Brazil in the capital of Santa Catarina state corroborates the findings that out-of-pocket payment for medicines are still having an impact on household budgets (Boing, Bertoldi and Peres, 2011). The study has reported

that more than 15% of family income was committed to purchasing medicines among the richest, compared to 9.6% in the poorest group. Around 29% of the adults studied bought medicines which are part of the Municipal List of Essential Medicines, and around 10% had to purchase medicines not obtained through SUS. Again, even if methodological differences make the results not directly comparable with the other studies discussed here, the data gathered suggest that the bottom income deciles still pay for medicines that should be available free of charge. In support of this suggestion, Bertoldi *et al.* (2010) reported that around 25.5% of the medicines obtained by the bottom income decile of the population are paid for entirely out-of-pocket. The situation remains in certain aspects unchanged if compared with 1998. According to data from PNAD, in 1998, among the poorest deciles of Brazilian households, the majority of health expenses went to purchasing medicines of regular use. In this share of the population, 22% of average family income was committed to purchasing medications for regular use (Silveira, Osório and Piola, 2002).<sup>51</sup>

That same pattern of medicines being the main source of expenditure among the poorest, and having its share reduced as wealth increased, has also been portrayed by other studies with some degree of variation within the proportions of expenditure (Barros and Bertoldi, 2008; Diniz, Eirado and Piola, 2007; Silveira, Osório and Piola, 2002). Another study that aimed to compare the proportion of medicine paid out-of-pocket with the proportion paid by SUS showed that the former represented 1.3% of the total income of the bottom decile families and 2.5% of income from the well-off families in the top decile (Bertoldi *et al.*, 2011). The amount of money paid out-of-pocket accounted for 26% of all health expenditures among the poorest decile families. On the other hand the research reported that SUS paid for 78% of the medicines used by the population in these socioeconomic strata. The relative proportion of medicines obtained free of charge according to the socioeconomic deciles analysed by the authors showed an inverse correlation: the higher the socioeconomic status, the lower is the contribution of medicines provided free of charge. In order to summarise the data about private expending on medicines, some of the key figures discussed are presented below in table 2.3.

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<sup>51</sup> This percentage refers to the families that had health expenses within the poorest population deciles. However, it is worth noting that, according to PNAD 1998, among the 10% poorest only 22% of people were in families who had undergone health spending, while among the 10% richest this proportion was 89%.

**Table 2.3– Percentage of private expenditure on health and medicines according to data from National Household Surveys**

Parameter	National Household Surveys			
	1988	1996	2003	2009
% health expenditure related to total income	5.3% (Diniz, Eirado and Piola, 2007)	7%(Silveira, Osório and Piola, 2002) 6.5%(Diniz, Eirado and Piola, 2007)	5.1%(Diniz, Eirado and Piola, 2007)	
% medicines expenditure related to health expenditure		37% (Silveira, Osório and Piola, 2002)	41% (Menezes, 2006)	
% medicines expenditure related to total income	2.32% (IBGE 1988)	2.65% (IBGE 1996)		2.8%(IBGE, 2010)

This section has highlighted the inconsistency in the assessment of the availability of essential medicines. Currently, there are no data to support conclusions on availability of essential medicines around the country, but data suggest that the level is still unsatisfactory. The literature has shown that, compared to other countries with similar health systems, public spending on medicines is not compatible with the systems of universal coverage that SUS is legally, and even constitutionally, bound to provide. This discussion on access finishes the literature review devised for this thesis.

In the following section I offer my conclusions on this review. Before we explore the main conclusions, let me highlight briefly how the points reviewed here connect to my research process. In the previous sections I explored a broad range of themes related to decentralisation, policy analysis and power. Although I have discussed a variety of frameworks that could potentially be used to analyse decentralisation processes, I did not follow any one approach consistently. Instead, I chose elements from each of them that I felt could inform my research. Decentralisation frameworks, health reforms dynamics and issues of implementation helped to understand some aspects that influenced the decentralisation of Brazilian pharmaceutical assistance, and contributed to refining my research questions. Moreover, the observation that there is no single approach suitable to analyse all dimensions of decentralisation highlighted the complexity of the subject, and uncovered many critical aspects that influenced my data collection and analysis. The importance of the agreement forums within the Brazilian federative arrangement was one of the aspects revealed by the literature review that influenced my choice of actors to interview. With regard to the interviews, being aware of aspects concerning concepts of power and its models was essential for

conducting and designing the interview guide. In this respect, power relations and its dynamics informed my approach to data analysis.

## **2.6 Conclusions**

As the different perspectives from academics in the field reviewed here have shown, decentralisation in health systems is a global, multidimensional phenomenon. Decentralisation is also highly dependent on each country's context regarding the governmental institutional structure, the legal framework and the intra-country negotiations arrangements. In the view of researchers, decentralisation is related to where power and responsibilities lie in the health system, i.e. where the decisions are made. As Saltman *et al.* (2007:10) put it, decentralisation is "...the transfer of authority and power from higher to lower levels of government or from national to sub-national levels". Power is distributed in a search for greater efficiency, equity and effectiveness, and although positive outcomes are claimed to be achieved by some authors, such as Bossert (2003) and Jutting *et al.*(2004), negative results of decentralisation are pointed out by others, such as Prud'homme (1995). These perceived advantages and disadvantages have given rise to debates about decentralisation and reversions to centralisation. As the scholars' standpoints reviewed here have suggested, decentralisation is a complex process that encompasses political, economic and fiscal dimensions, each of them with different, and at times conflicting, objectives and consequences. Decentralisation results are difficult to measure and no single or universal analytical framework is capable of reflecting all the dimensions involved. Moreover, there is no definitive evidence on the results of decentralisation. It is difficult to distinguish whether a change is in consequence of decentralisation or of other factors. The multidimensional feature of decentralisation and the limitations in analytical frameworks, along with the aspects that each framework can assess, were important elements that helped inform my decision of where and how I could investigate to answer my research questions.

A brief overview of the vast body of literature concerning issues of power, especially related to policy process, was reviewed in this chapter, providing important elements to inform my research design and support my analysis. The literature reviewed has shown that understanding the dimensions of power and how it can be exercised is crucial to interpreting the influence of the diverse actors and their motivations in policy changes introduced by decentralisation.

Integrating the literature on decentralisation discussed in this chapter with the health reforms that have occurred in Brazil and in decentralisation of pharmaceutical assistance explored in Chapter One, contributed to drawing a broader view of the context within which decentralisation has occurred, as well as the theory and concepts involved. In sum, as acknowledged by Regmi *et al.* (2010), the literature on decentralisation, though large, has paid comparatively little attention to the impact of decentralisation on the management and delivery of health services. Even less emphasis, perhaps not surprisingly, has been placed on the effects of decentralisation on pharmaceutical assistance in Brazil. The most apposite research in this last respect has tended not to link decentralisation to the issue of access to medicines in a thorough manner. Typically, for example, the study conducted by Barreto and Guimarães (2010), which evaluated the decentralised management of pharmaceutical services in municipalities, did not address access but, instead, focused on the evaluation of management and, more specifically, on organizational and operational aspects of service delivery. Moreover, other studies that I have analysed, such as Chaves *et al.* (2005), have evaluated access to medicines but have not related the topic to decentralisation policies.

Adequate availability of medicines free of charge is still an issue, and the data available do not support consistent progress in levels of access around the country. Overall, expenditure on medicine has increased, although the evidence here discussed suggest that growth is concentrated on high cost drugs and not on essential medicines for primary care. Expenditure on medicine swallows up a significant amount of the household income among the poorest income levels. Literature assessing access to medicines in Brazil, although scarce, confirms the relevance of my research to exploring how public provision of medicines is managed under the decentralised model, and if it has had an impact on access. Hence, these perceptions are encouraging justifications of the novelty of the research proposed by my thesis. Some scholars here reviewed, such as De Vries (2000) and Prud'homme (1995), reported an increase in inequalities as a result of decentralisation; hence, regional differences in terms of availability of medicines experienced in Brazil could be related to the decentralised management adopted. The lack of definitive evidence in the results and the difficulties in measuring decentralisation speak of the complexity of trying to assign the role of decentralisation in the context of the public provision of medicines in Brazil. These observations from academics, discussed in this review, have helped to shape my approach to the design and conduct of the research reported in this thesis. I will explore these ideas and limitations in more detail in the next chapter when discussing the methodology and the research design of my study on decentralisation and its impact on access to essential medicines.

## CHAPTER THREE

### RESEARCH DESIGN AND METHODOLOGY

#### 3.1. Introduction

The preceding chapter placed my investigation in the academic and policy context but also alluded to some of the methodological issues and uncertainties encompassed by the complex and multifaceted question of how decentralisation of basic pharmaceutical assistance affected access. Addressing these considerations, this chapter introduces the research methodology used for this study. I will provide a conceptual rationale for the approach taken to the research and a detailed description of the methods used. A brief discussion of the epistemological foundations of the research design, premised upon pragmatic critical realism insights based on the views of McEvoy and Richards (2003), is followed by an explanation of the data collection strategy. The subsequent section explains the rationale for a particular focus upon decentralisation policy as it has been applied to primary care medicines (for example, Type 2 diabetes and hypertension) in Brazil. The discussion then focuses on the approaches taken to sampling and data sources, the development of research instruments, piloting of the research and the techniques used to analyse the accrued data. Before I discuss my research methodology, I will give an overview of my professional experience and how it has influenced my research.

I worked for 15 years in the Department of Health of the Federal District, at the blood bank of the capital of the country. In those years I represented this public institution on various committees and local and regional meetings. These activities have allowed me to observe the relationships between health institutions within the Federal District, and between the federal and local level respectively. Many of these meetings dealt with problems and failures in implementing policies and compliance with regulations. Blood banks are heavily regulated from the point of view of health surveillance due to the nature of their activities (collection and blood transfusion) linked to the restoration of health, but if regulation is poorly implemented it can cause damage to health (such as blood transfusion contaminated with Hepatitis C due to a failure in the implementation of screening procedures). In another health related job that allowed me to participate directly in policy-making; I was involved with the development of policies and regulations pertaining to in vitro diagnostic tests at ANVISA (National Agency of Sanitary Surveillance). In this role I also represented the federal government at national meetings and within MERCOSUR (Common Market of the South). Finally, an additional professional experience that has proven useful for my understanding of the complexities inherent in my topic of research has been my work as a consultant in the regional parliament on matters relating to health (since 2006). In this role I have come into direct contact

with the failures that occur in SUS pharmaceutical assistance. Because my role is to support the drafting of local bills, and also provide advice on matters related to public health in the Federal District I became interested in the provision of essential medicines at the local level. As a consequence I became conscious of the intricate relationships between the tiers of government in the implementation of health policies, and realized that there is an excessive volume of policy documents and regulations to which I needed to pay attention in order to understand the field.

### **3.2 Conceptual foundations and the research design**

In the preceding chapter, I argued that broad reforms such as decentralisation in health care are often driven by a variety of ideological and practical objectives and typically have unpredictable outcomes for which criteria of measurement and evaluation are difficult to anticipate on an *a priori* basis (Pawson *et al.*, 2005). In terms of the epistemological foundations of my research design, an empiricist focus upon clarifying how simultaneous processes of decentralisation and recentralisation have affected access to essential medicines would have been problematic in two respects. First, the multi-sectoral and multi-actor nature of the decentralisation initiatives meant that I needed a methodology that allowed me to consider the situated interpretations and motivations of relevant stakeholders. This involved fluid perspectives and understandings that might shape and reshape understandings of reality with regard to policy inputs, processes and outcomes.

Second, since the interpretation and interpolation of stakeholders' views becomes central to the research enterprise, it becomes very difficult to completely write out the judgement and selectivity exercised by the researcher. In trying to generate and explain a picture of reality, the basis of the planned research gravitated towards a pragmatic critical realism (McEvoy and Richards, 2003; Yeung, 1997). This approach – often associated with the philosophical insights of Bashkar (1998) and Harré (1970) – is premised upon three ideas relevant to my research. First, as McEvoy and Richards (2003)<sup>52</sup> observe, pragmatic critical realism does not shy away from interpretivist approaches in understanding the rationales and actions of informants. This is not to dismiss the reality of existing legal and administrative structures and processes but is, instead, an

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<sup>52</sup> As very well summarised by Yeung (1997:52), critical realism, the hallmark of the Bhaskarian version of scientific realism in the social sciences, is “a scientific philosophy that celebrates the existence of reality independent of human consciousness (realist ontology), ascribes causal powers to human reasons and social structures (realist ontology), rejects relativism in social and scientific discourses (realist epistemology) and reorientates the social sciences towards its emancipatory goals (realist epistemology)”.

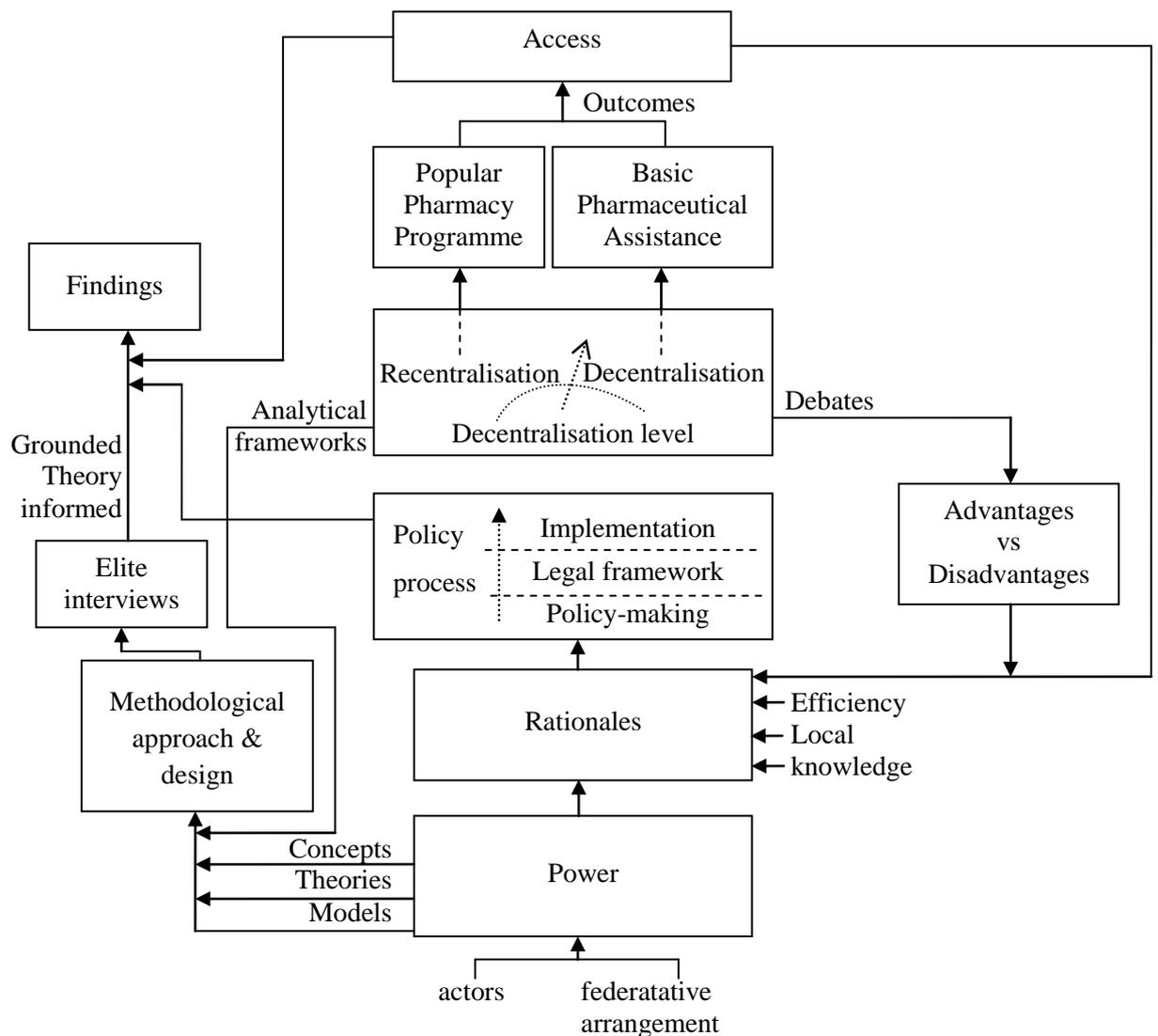
acknowledgement that the phenomena under study can often be interpreted, challenged and reacted to in a multiplicity of ways by key actors. In a second related respect, pragmatic critical realism will acknowledge the multiple fields, domains or levels of perception and behaviour that can operate simultaneously (sometimes in unison and sometimes discordantly). For instance, enthusiastic proponents of decentralisation at the federal, state and municipal levels may evince similar ideologies and objectives, but their distinct parameters of action and experiences might influence their interpretation and evaluation of specific initiatives. A third premise associated with the approach is associated with this reality: the fields, domains or levels are not necessarily sealed off from one another. They may be susceptible to challenge, interpolation and blurring by actors therein – and this is particularly the case in relation to lobbying by interest groups (McEvoy and Richards 2003: 412-413). These three epistemological foundations pointed to the need for a research design that allows ‘triangulation’ of methods. A design was needed that would give research participants a voice of their own and define the role of the researcher as somebody who interprets and orders ideas in the light of research objectives and insights from relevant academic literature. In this respect, triangulation and multimethod research have been proposed as a way to enhance validity of research findings (Bryman, 2012:635). Triangulation is often used in qualitative research as a way of achieving a multi-faceted portrayal of the context within which the topic is studied (Hollar, 2008). These two features, enhancing validity and a comprehensive portrayal of the context, made triangulation of much interest in my research design.

Combined approaches are not without their critics. One criticism is that different research methods are rooted in wider epistemological and ontological perspectives that may not be compatible with each other. Morgan (1998) argues that differences between qualitative and quantitative methods in the nature of the knowledge produced and the means to generate knowledge make the information and knowledge created by each method incomparable in many situations. Although Morgan (1998) also argues that the tenability of combining qualitative and quantitative methods in a research design is not determined at this conceptual level – such viability instead depends upon the nature of the proposed research and the internal logic of the research design. This point of view, called a “technical” approach by Bryman and Beevan (2005:323), informed my approach to the research design. Specifically, a mixed methods approach would facilitate description, triangulation and interpretation from different perspectives but, as acknowledged by Creswell (2009), would also necessitate a clear idea of the juxtaposition and purpose of each element of the investigation.

Taking these considerations on board, data collection and analysis in this thesis are informed by principles of the Grounded Theory approach (Glaser and Strauss, 2009) observing the alternative perspective proposed by Charmaz (2006). In this respect, the research described here centred on

three sets of activity, each informing and shaping the other. An (i) initial ‘policy review’ and interpretation of public domain policy documents, associated commentaries and academic publications (summarised in Chapter Two of this thesis) helped to inform; (ii) the identification of key informant interviewees whose insights might be particularly illuminating in exploring how political and power dynamics have influenced the provision of medicines in Brazil. This review also served to illuminate (iii) sources of quantitative data with regard to the dynamics and progress of the decentralisation of pharmaceutical services in Brazil.

In order to make clear the role of each element within the research design, Figure 3.1 represents, in a model, the interactions and influences of each element in my research process.



**Figure 3.1. Research process**

Source: author

The three sets of activities are shown in Figure 3.1. The figure illustrates the work flow of my PhD research. The central and right sides of the figure represent the literature review – the first step in the research process. The ‘policy review’ comprises the analysis of elements involved in the policy-making, legal framework and implementation of decentralisation of pharmaceutical assistance. As indicated, the identification of actors and the dynamics of power inherent to decentralised settings emerged from the analysis of concepts, theories, and models concerning power and decentralisation conducted in the literature review, and this informed my research design, the second step carried out, which is represented on the left hand side of the figure. The dynamics of decentralisation and responsibilities of each level of the federation regarding the provision of medicines pointed to the role and weight of Ministry of Health officials, state and municipal health secretaries. The identification of those actors led to the choice of elite interviews as the preferred method to help answer my research questions. The Grounded Theory approach informed my data collection and analysis, which constituted the third step in my research, is also represented on the left hand side of the figure.

In the following section I will detail some aspects of Grounded Theory that help to explain the adequacy of this approach to the purposes of my thesis.

### **3.3 Overview of the Grounded Theory Method**

Glaser and Strauss’s (2009) influential book *The discovery of Grounded Theory*, was notable as a response to the predominantly quantitative research paradigms when it was first published in the late 1960s, and an answer to criticism about the scientific rigor and value of qualitative research. In their book Glaser and Strauss proposed an approach to systematic qualitative analysis and offered practical guidelines. They argued that qualitative research employing the proposed systematic approach would generate theory, contrasting it with positivism, which aims to test a hypothesis from an existing theory. Soon Grounded Theory became one of the most popular research methods used in qualitative research among social scientists. While Glaser and Strauss form the first generation of grounded theorists (Birks and Mills, 2010:3), those who interpreted Glaser and Strauss’ methods, the second-generation grounded theorists, include scholars such as Kathy Charmaz, Leonard Schatzman, Barbara Bowers, Juliet Corbin and Adele E. Clarke. After the methodological split between Glaser and Strauss in 1992 they assumed different perspectives on Grounded Theory. The split followed the publication of Strauss and Corbin’s text *Basics of qualitative research: grounded theory procedures and techniques* (1990) which was strongly

contested by Glaser as not being Grounded Theory but proposing a new method (Walker and Myrick, 2006). Differences in epistemological perspectives resulted in three main categories of Grounded Theory: Classic (or Glaserian) Grounded Theory, Straussian Grounded Theory, and feminist or constructivist Grounded Theory.

Charmaz' approach, a variant of constructivist Grounded Theory, was influenced by feminist and constructivist methodological work, reflected in the focus on the place of the author in the text, their relationship with participants, and the importance of writing in constructing a final text that remains grounded in the data (Birks and Mills, 2010). The process of writing, according to Charmaz, is involved in the development of the theory. This process allows for insights and ideas about the data to emerge. Writing and rewriting constitute essential parts of the analytical process involved in Grounded Theory. Charmaz (2006:9) argues that "the flexibility and legitimacy of Grounded Theory continues to appeal to qualitative researchers with varied theoretical and substantive interests". As Charmaz remarks, basic Grounded Theory guidelines describe the steps of the research process, which can be adapted to serve in different studies. Grounded Theory methods include key strategies for conducting data collection and analysis. Data collection usually consists of interviews but can also include other sources of data such as existing research literature and quantitative data, whereas data analysis includes coding, comparisons between data, theoretical sampling and memo writing. Theoretical sampling is a form of purposive sampling where participants are selected according to criteria specified by the researcher and based on initial findings. Considering these aspects, especially data collection using interviews and the possibility of using purposive sampling, my methodological approach was informed by Grounded Theory. The Grounded Theory research approach, however, is not without controversy and has limitations like any other research methodology. Some argue that the Grounded Theory method is very time-consuming due to the coding process and memo writing as part of the analysis. This same characteristic, however, is considered an advantage of the method as coding "keeps your project going", in the words of Kathy Charmaz.<sup>53</sup> To others, Grounded Theory is very subjective as it relies heavily on the researcher's abilities. Many studies make use of the term Grounded Theory inappropriately (Egan, 2002), and Bryant (2002) points out that the flexibility of the method can be used to provide a justification for studies lacking in methodological strength.

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<sup>53</sup> BSA Med Soc 2012- University of Leicester-UK- Professor Kathy Charmaz presented "The power and potential of Grounded Theory". Available from <http://www.youtube.com/watch?v=zY1h3387txo>. [Accessed 20 June 2013].

### **3.4 Rationale for the focus on medicines to treat hypertension and type 2 diabetes**

As the preceding chapters indicate, decentralisation of pharmaceutical services has encompassed myriad administrative bodies, several layers of administration and governance and a broad range of medicines. My research thus had to focus on selected technologies that were of implicit or explicit interest to large sections of the Brazilian population and had significant implications for funding decisions - in terms of demand, cost and use. In this regard, my own professional experience in the sphere of Brazilian public health and knowledge of attendant epidemiological and policy sources pointed to two particularly apposite conditions – hypertension and type 2 diabetes. The medicines to treat both conditions are classified as essential medicines.

There are sound reasons for choosing to understand changes in the provision of these particular medicines. According to the Ministry of Health, Brazil has 33 million people with hypertension. This prevalence increases with age and the condition is associated with cardiovascular, brain, coronary, renal and peripheral vascular complications. It is estimated that 40% of strokes and about 25% of heart attacks occurring in hypertensive patients could be prevented with appropriate antihypertensive therapy. Diabetes mellitus is a challenge for health systems around the world, and in 2010, Brazil was among the five countries with the largest number of people with diabetes (International Diabetes Federation cited in (Diabetes UK, 2010)). The consequences of diabetes in human, social and economic terms are severe. The condition can lead to cardiovascular disease, necessitate dialysis for chronic renal failure and result in surgery to amputate lower limbs. In global terms, four million deaths per year across the world are directly attributable to the disease or associated complications (accounting for 9% of all deaths). Diabetes, like hypertension, thus has major cost implications for health systems. The availability and accessibility of drugs to treat both conditions are necessarily focus of concern to for a large swathe of the patient population and, thus, to health policy makers and politicians. Indeed, in 2008 the National Household Survey (PNAD-Pesquisa Nacional por Amostra de Domicílio) showed that 14% of the Brazilian population had reported hypertension and 3.6% had indicated that they suffered from diabetes. Diabetes and hypertension are also the leading cause of hospitalisation in the public health system within Brazil. One study, for example, of the economic impact of diabetes in the country, encompassing 37 million hospitalisations between 1999 and 2001, estimated that 2.2% of the Ministry of Health's annual budget was devoted to acute and out-patient hospital care for diabetes (Rosa and Schmidt, 2008). Therefore, to focus on the provision of these medicines could represent a very reasonable parameter for my research to track changes resulting from decentralisation.

### 3.5 Sampling and data sources

This focus upon hypertension and diabetes, coupled with the rationale for qualitative interviews described above, necessarily influenced my study's approach to sampling. In particular, the fluid and porous population of interest does not allow the delineation of a stable sampling frame and true randomisation in the choice of potential informants (O'Leary, 2009: 166). The default sampling technique thus pointed to study recruitment based upon purposive selection, snowball sampling, theoretical sampling and opportunistic or pragmatic engagement of informants<sup>54</sup> (Bowling, 2009:409; Bryman and Teevan, 2005:227-233). More specifically, purposive and snowball sampling techniques were particularly relevant for this study, given that my focus was upon policy-making *elites* as identified by Tansey (2007) and Erasmus and Gilson (2008). The idea of elites is not, of course, unproblematic (Harvey, 2011). Some scholars, for example, suggest a hierarchy of status within apparently homogenous elite groups ('ultra elites'). Others classify groups according to professional competence and skills - professional elites sit at the pinnacle of such hierarchies. Smith (2006) and Harvey (2010), however, reject the idea of job titles or professional positions as straightforward indicators of elite status. Indeed, those who hold strategically important positions within influential social networks could legitimately claim elite status beyond that of more visible figureheads and leaders within organisations or policy domains (Harvey, 2011; Harvey, 2010).

As acknowledged by Goldstein (2002), potential problems with sampling bias or the impact of non-response from key informants – a non-random error rather than a problem with approaches to measurement – were thus not automatically obviated by a focus upon interviewing elites (Goldstein, 2002). Moreover, time constraints, crowded agendas and caution might limit the cooperation of this type of informant - coupled with a relatively small sample size – potentially raising the possibility of highlighting skewed perspectives. Moreover, such failures could compensate for random errors in the form of misconceptions, distortions or simple lies on the part of participants. As Goldstein (2002) notes, however, elite interviews may have an advantage over broader sampling strategies. Participants, if they are forthcoming, may not only provide credible

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<sup>54</sup> *Convenience sampling*: subjects are sampled according to accessibility. The sampling is based on the facility of recruiting, availability or likelihood to respond. Some sort of convenience sampling might occur mixed within the other two forms of sampling described below.

*Snowball sampling*: is considered a variation of convenience sampling by Bryman and Teevan (2005:227) since there is no sampling frame. Researcher makes contact with a small group of potential respondents relevant to the subject. These initial respondents are asked to suggest others whom they know are in the target group and this process is repeated successively.

*Theoretical sampling*: is an essential part of Grounded Theory. The researcher simultaneously collects and analyses data, decides what data and where to collect it next, and develops a theory as it emerges. The process is carried out until a theoretical saturation point is reached, that is when no new analytical insights emerge. The objective is the advancement of ideas rather than boosting sample size.

testimony but can also identify other, perhaps less obvious, informants and could be in a better position to buttress their views with official documentation or other evidence. In addition, these additional informants and new sources of evidence may in themselves triangulate and verify the statements and interpretations of the elite informants. I took these considerations into account when dealing with my sample, and checked continuously against policy documents, databases and probing another interviewee when I encountered unusual views or information. As Prainsack and Wahlberg (2013:339) remind us, elite participants “are often guarded and weary of how what they say will be received in ‘the public’.” They argue that elite groups are cautious about outsiders, in this case the researcher, who could disclose to the public the disordered and discontinuous character of the policy-making as it actually occurs. That exposure would thwart the elite’s efforts of being seen as “formulating rational and coherent policies” (Prainsack and Wahlberge, 2013:348).

### **3.5.1. Identifying key sources**

The review of policy documents, knowledge gained in my professional experience and personal contacts were used to inform the selection of potential participants. The sample was designed on the basis of maximum possible variation – a reflection of the fact that “no matter the goal, good research practice demands that one use multiple sources” (Goldstein, 2002:699). Actors across the three levels of government that were considered for this research included Municipal Health Secretaries, State Health Secretaries, and officials from the Department of Pharmaceutical Assistance and from the Department of Interfederative Relations of the Ministry of Health. As discussed in Chapter One, the Ministry of Health plays the prime role in health policy-making in Brazil. The federal level of administration controls the largest proportion of funding in the health field and sets attendant regulations for the use of these resources. Officials from the Department of Pharmaceutical Assistance, specifically those directly involved with the implementation of decentralisation policies, were identified as suitable interviewees. Health Secretaries at the state level were also approached on the basis of their fundamental role in the coordination of pharmaceutical assistance at a regional level. The target sample also reflected the municipal level of administration’s essential role with regard to access to medicines - this is the level at which drugs are made available to patients through many publicly managed facilities. Consideration was also given to the geographical variations discussed in the previous chapter. Senior personnel at municipal and state level within each of the five Brazilian geographical regions were selected in order to address this requirement.

Accordingly, three sources of data were used in this research: i) semi-structured interviews; ii) national databases; and iii) literature and policy documents. Primary data were obtained from semi-structured interviews with key stakeholders in the domain of pharmaceutical assistance policy,

particularly those involved directly in the decentralisation/recentralisation processes across the three tiers of government. In subsequent sections in this chapter I will describe the interview procedure in more detail.

Academic literature, policy documents and statistical databases related to access to basic medicines in Brazil, reviewed in Chapters One and Two helped, first, to anchor and orientate the foci of the investigation with regard to access to medicine. Second, this review helped to contextualise and corroborate findings derived from interviews. The main aspects identified and addressed in the analysis of documentation which helped to design my sample were:

- Responsibilities in the pharmaceutical assistance cycle regarding essential medicines, within each governmental tier as prescribed by legislation;
- Initiatives at each governmental level that aimed to improve access to medicine;
- Decentralisation and recentralisation initiatives within the pharmaceutical assistance policy regarding basic medicines and, where possible, diabetes type 2 and hypertension drugs.

### **3.6 Developing the interview guide**

Qualitative interviews have been a common research method in the social sciences since the pioneering work on the urban experience by the Chicago School in the 1930s and 1940s (Kvale and Brinkmann, 2008:9). Qualitative interviews can be unstructured, semi-structured or employ a mixture of both approaches. The strategy in unstructured interviewing is to adopt a conversational style. In such cases, the interviewer usually has a brief list of themes or key words rather than a set of fully written questions – the emphasis is upon flexibility and fluidity in the interview in order not to constrain the interviewee or ignore potentially relevant insights. These face-to-face in-depth interviews “aim to delve deep beneath the surface of superficial responses to obtain the true meaning that individuals assign to events, and the complexities of their attitudes, behaviours and experiences” (Bowling, 2009:407). When more specific information is required, however, a semi-structured interview format may be more appropriate. In this format the researcher employs an interview guide with a list of questions or specific topics to be covered. There is still scope for flexibility in the reformulation of questions, follow-up questions and freedom of expression on the part of the interviewee, but it is assumed that all issues addressed by the schedule will be covered (Silverman, 2010:136). Semi-structured interviews allow respondents to reflect and organize their answers, which in turn potentially increases the validity of the responses (Aberbach and Rockman, 2002). Qualitative interviews can also be conceptually “active” in that they might allow interviewees to confirm, develop or refute initial formulations and ideas with regard to the research on an ongoing basis (Silverman 2010: 136).

As with any other research method, qualitative interviews have advantages and disadvantages. Advantages over quantitative methods, such as structured self-completion questionnaires, include the potential to obtain more detailed and nuanced information and scope for the researcher to address more complex and fluid issues. Potential disadvantages include the relatively time-consuming and resource-intensive nature of interviews compared, for example, to Internet-based questionnaire surveys. This can have implications for sample sizes in interview research and thus may raise questions about the degree to which data can be said to represent the wider population of interest (Bowling, 2009:408). Kvale and Brinkmann (2008: 105), however, observe that interviews alone are seldom used to test quantifiable hypotheses. They are more often oriented to understanding the inner rationales, emotions, attitudes or social behaviour of interviewees. Moreover, in many cases interview research will be concerned with advancing the understanding of complex phenomena rather than simply gathering descriptive data (Bowling, 2009:410). Against this background, my development of the interview instruments followed the guide proposed by Bryman and Teevan (2005) and data analysis strategy was informed by Grounded Theory as propounded by Charmaz (2008: 82). Regarding the interviews, in the subsequent subsections I will explain how I designed my interview guide and discuss how I prepared myself to conduct the interviews.

### **3.6.1 Preparing the interview guide and piloting**

The interview guide was prepared in accordance with the guidance produced by Bryman and Teevan (2005: 187) and was developed with specific reference to themes identified in the literature review around power, decentralisation and pharmaceutical assistance policy. The interview guide was essentially the same for the four different categories of interviewees (CONASS - National Council of State Health Secretaries members, CONASEMS - National Council of Municipal Health Secretaries members, Ministry of Health officials and National Health Council representatives).<sup>55</sup> The wording was, however, sufficiently flexible to allow for different emphases to be raised in the discussions.

Upon these bases, the interview guide was piloted with the cooperation of two municipal Health Secretaries to refine the wording and sequence of the questions. The pilot phase was also helpful in establishing the likely length of interviews. As a result of the piloting, the guide was revised slightly (the interview guide is in Appendix 3).

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<sup>55</sup> Refer to Chapter One for details on these forums.

### 3.6.2 Preparing to enter the field

Kvale and Brinkman (2008: 166-167) emphasise the importance of the interviewer as an agent or “variable” within interview enquiry. The authors compare the interviewer to an able craftsman who – to a greater or lesser extent – has a grasp of interview techniques and reflects characteristics that enable him or her to be a successful interviewer<sup>56</sup>. This set of desirable characteristics is further extended by Bryman and Teevan (2005: 187) to encompass several aspects such as: knowledgeable, structuring, clear, gentle, sensitive, steering, critical, remembering, interpreting, balanced, and ethically sensitive.

The interviews should, if possible and with the interviewee’s permission, be audio-recorded in order to facilitate detailed analysis. Recording the interview will also allow the researcher to focus on the conversation without worrying about taking detailed notes. Additionally, some notes should be made during the interview and immediately afterwards. As remarked by Bryman and Teevan (Bryman and Teevan, 2005) this guards against equipment failure and poor recording quality and can aid analysis (Bryman and Teevan, 2005: 191). Conducting my interviews I was also aware of possible anxiety about being recorded on the part of the interviewee. The authors state that if the researcher judges that information has been withheld the recording device should be turned off at the end of the interview (or at relevant junctures) so that interviewees can be encouraged to speak more freely.

Recording and transcribing interviews has further advantages. As Bryman and Teevan (2005: 191) observe, this facilitates scrutiny of data by other researchers; helps to counter potential accusations of bias in the analysis and leaves the data open to further analysis by the original investigator or others. Transcribing interviews, however, is time-consuming – it may take five to six hours to carefully transcribe an hour of recording (Bryman and Teevan, 2005: 191). Transcription can of course be out-sourced where resources allow, but this delays “immersion” in the data by the analyst and places judgements on grammar, punctuation and layout in the hands of a third party.

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<sup>56</sup> The extent of spontaneous, rich, specific, and relevant answers from the interviewee; the extent of short interviewer questions and longer interviewee answers; the degree to which the interviewer follows up and clarifies the meanings of the relevant aspects of the answers; to a large extent, the interview being interpreted throughout the interview; the interviewer attempting to verify his or her interpretations of the subject's answers over the course of the interview; the interview being "self-reported," a self-reliant story that hardly requires additional explanations.

### **3.7 Data collection procedures**

Data collection was based on semi-structured interviews that were conducted with key respondents across the three tiers of government (federal, state and municipal). Twenty interviews were conducted, and some informal talks with Ministry of Health officials occurred in October and November 2011 in Brasilia, Brazil. On average, the interviews lasted 40 minutes (ranging from 15 to 85 minutes). The interviews were concentrated within a short period due to time and resource constraints. I planned and pre-arranged the interviews to take place in Brasília in a period covering a national meeting (Tripartite Intergovernmental Commission-CIT meeting) attended by municipal and state health secretaries from all Brazilian regions. I also interviewed health secretaries in the days preceding the CIT meeting when they had preparatory meetings involving both CONASS and CONASEMS. Ministry of Health officials and National Health Council (CNS) representatives work in Brasília and were interviewed over the days after the CIT meeting. All interviews were recorded and transcribed. On top of the transcriptions (in Portuguese), I also translated into English the parts that correspond to quoted extracts I used in my reporting. This added even more time to the transcription task.

#### **3.7.1 Interviewees**

I conducted twenty interviews distributed as follows:

- a) State Health Secretaries (5);
- b) Municipal Health Secretaries (9);
- c) Ministry of Health Officials (4):
  - a. Department of Pharmaceutical Assistance:
    - i. Current director;
    - ii. Previous director;
    - iii. Basic Pharmaceutical Assistance Coordinator.
  - b. Department of Federative Relations:
    - i. Current director
- d) National Health Council representatives (2):
  - a. Rural workers union representative;
  - b. Intersectional Medicines Policy and Pharmaceutical Assistance Commission Coordinator.

It is relevant to justify the choice for interviewing CONASS and CONASEMS representatives; this was because eighteen out of twenty interviewees were currently or formerly health secretaries,

either municipal or state. The exception was a Ministry of Health official, and a rural union representative of the National Health Council. Moreover, all state secretaries interviewed were former municipal health secretaries. State secretaries interviewed were representatives of CONASS, and the municipal secretaries were representatives of CONASEMS. The distribution of the health secretaries interviewed according to their region is shown in Figure 3.3.

**Table 3.1 Health secretaries interviewed according to region.**

Region				
North	Northeast	Midwest	Southeast	South
<b>Amapa</b> State Health Secretary	<b>Ceara</b> State Health Secretary		<b>Sao Paulo</b> Municipal Health Secretary (3)	<b>Parana</b> State Health Secretary Municipal Health Secretary
<b>Amazonas</b> Municipal Health Secretary	<b>Bahia</b> State Health Secretary Municipal Health Secretary		<b>Minas Gerais</b> Municipal Health Secretary (2)	<b>Santa Catarina</b> Municipal Health Secretary
	<b>Sergipe</b> State Health Secretary			

Regarding the viability of the achieved sample, it covers four of the five geographical regions of Brazil. I intended to cover all five regions, and actually pre-arranged interviews, but unfortunately due to unforeseen circumstances I was unable to interview any health secretary from the Midwestern region. While this was not the ideal situation in terms of responses from the five regions, I live in Brasilia, which is located in the Midwest, and I worked in the Federal District Health Secretariat until 2006. Therefore, although I was unable to interview the health secretary in Brasília, I did talk to two Federal District Health Secretariat officials to check if my knowledge of the pharmaceutical assistance situation was still valid.

Although not all 27 federative state members were interviewed, the members who participated are part of CONASS or CONASEMS. They take part in the CIT meetings, which are the final forum in the process of negotiation within the Pharmaceutical Assistance Policy in Brazil. Moreover, some of them are very experienced and have been working in the area for 15 to 20 years or more. Some

took part in the *movimento sanitaria*, which played an essential role in the origins of SUS. Concerning the Ministry of Health officials, by interviewing both the previous and the current director of the department of pharmaceutical assistance there was an overview of policy-making and implementation over the last 10 years. I believe that these qualifications speak for the expertise of the interviewees regarding the public provision of medicines, and therefore corroborate my choice of elite interviews as an adequate tool for my investigation.

### **3.8 Data analysis**

#### Coding and comparing data

For this work I transcribed each interview and saved the work in separate files. I wrote memos after each transcription to keep track of thoughts and ideas regarding the data analysis. Transcripts were coded in at least three sequential 'rounds' observing Charmaz's (2006:43-71) guidelines on coding. The essential role of coding is well explained by Charmaz (2006:46) as being 'the pivotal link between collecting data and developing an emergent theory to explain these data'. I worked through each of the transcripts, coding incident to incident. Codes devised varied from those very close to the interviewees' accounts to other more conceptual ones. I have provided a worked example of coding in Table 3.2. In the example given, initial codes identified different processes (verbs ending in 'ing') related to intergovernmental relationships. This included a group of codes that captured my respondents' experiences with intergovernmental pacts that governed decentralisation process. Because accomplishment with these pacts seemed central to the implementation of decentralisation, and because it was talked about often, "disruption of pacts" became a focused code. By comparing codes against codes, and data against data, I was able to distinguish the category "disruption of pacts" from other focused codes, such as "roles and responsibilities: coordination, interdependence and autonomy" and to understand the relationship between them. In the example, using this constant comparative method I created a theoretical code: "interference of federative relationships in the implementation of decentralised policy".

Codes and later categories were grouped under four main themes built from major theoretical codes: decentralisation and centralisation of public provision of medicines; federative relationships in decentralised setting; basic pharmaceutical assistance and access; and popular pharmacy programme. I organised the codes and categories under each theme in four main tables. More representative codes/categories' quotes were saved and assigned a position number that allowed data to be retrieved within each interview transcript. Each of these four themes originated a chapter (Chapters Four to Seven). The findings from interviews were compared to the reviewed literature, relevant policy documents and legislation, which helped and supported the formation of conclusions.

**Table 3.2 – Coding process**

Raw data	Initial coding	Focused coding	Theoretical coding
<p><i>Q. Was there anyone against decentralising pharmaceutical assistance?</i></p> <p>The central question in Bahia was not only the agreement process itself. The issue was to ensure that what was agreed would be fulfilled, i.e., compliance with the covenants made in the political arena of the CIB [interstate forum].</p> <p>It was a source of tension between managers, but there was also negotiation and consensus. However, some agreements were not respected, and the state justified the breach of covenants as budgetary or financial difficulties. The state, instead of exercising technical cooperation to support the municipalities in the management of Pharmaceutical Assistance, to help municipalities to strengthen management capacity, and the implementation of pharmaceutical assistance policy, the state did the reverse. So, by failing to empower municipalities it was as if the state had boycotted what had been agreed. (Interviewee 4, 6.1).</p>	<p>Identifying what was beyond negotiation</p> <p>Pointing out the difficulties</p> <p>Recognising the potential of interstate forums: tensions and consensus Pointing out the state level failures in fulfil agreements.</p> <p>Explaining the failures</p> <p>Exposing disappointment with the state level administration</p>	<p>Disruption of pacts: failures and lack of accountability</p>	<p>Interference of federative relationships on the implementation of a decentralised policy</p>

### 3.9 Ethical considerations

Ethical considerations are an essential aspect of research involving human participants (Creswell, 2009: 87; Kvale and Brinkmann, 2008: 61-63). In my investigation, I sought to consider in particular ethical concerns as summarised by Kvale and Brinkman (2008: 63) related to research using interviews.

In addition to being aware of and ready to address ethical concerns that could be involved in the research process, before beginning the interviews, ethical approval was sought and obtained by submission of a completed *pro forma* to the Department of Sociology and Communications at Brunel University (acting on behalf of Brunel University Research Ethics Committee). As prescribed by Creswell (2009: 89), each interviewee was asked to read and sign an informed consent form that stipulated their rights in the research process. This form provided information about the purpose of the research, assured participants that participation was voluntary, indicated that they could withdraw from the research at any point and stressed confidentiality and anonymity.

All respondents gave their informed consent in writing (I retain the signed documents). Confidentiality was protected by anonymising the data, so that participants cannot be identified.

It should be noted as well that all my interviewees were administrators or policy makers who have experience with being interviewed and are not considered a particularly vulnerable population in any respect.

### **3.10 Summary**

This chapter described the research design and methods used in the investigation. It outlined the rationale for the fieldwork design and considered the issues of sampling, instrument development, data collection, and analysis. In sum, I designed and conducted my investigation on how decentralisation affected the provision of medicines mainly based on the strategy devised by Kvale and Brinkmann (2008) and Charmaz (2006). The themes explored in the literature review related to analytical frameworks used to evaluate decentralisation as well as the concepts, theories and models involved in research into power dynamics in policy changes were essential to my research design. The literature review shed light on important aspects which I considered to devise my research design, basically, how and where I should investigate to answer my questions but also who would participate in the process and the interest/power involved. I focused my work on elite groups – state or municipal health secretaries and Ministry of Health administrators – to study how decentralisation has come to be organised and implemented.

The research findings are presented in the next four chapters. Chapter Four explores how the decentralisation of provision of basic medicines has developed and who the main actors and rationales were in this process. Chapter Five explores how the federative arrangement and the consequent intergovernmental relations have affected the decentralisation of public provision of

medicines. Chapter Six discusses the changes in the public provision of medicines after decentralisation. Chapter Seven explores the implications of the Popular Pharmacy programme for the decentralised context of pharmaceutical assistance. Chapter Eight presents the conclusions, summarises the findings, and offers the closing remarks.

## CHAPTER FOUR

### DECENTRALISATION AND RECENTRALISATION OF PUBLIC PROVISION OF BASIC MEDICINES

#### 4.1 Introduction

In Brazil, the two most prevalent forms of medicine provision are (1) free supply, and (2) out-of-pocket direct payment by users. As in many other countries, the Brazilian health system is constituted of a complex network of services, which mix public and private providers (Paim *et al.*, 2011). Users of the private system, that is, those who have private health plans, buy drugs in pharmacies and pay out of pocket. They could use SUS pharmacies to obtain their prescription, but the chronic lack of availability of medicines in SUS push users of the private system to community pharmacies. SUS users, instead, receive medications free, but when prescribed drugs are not available in SUS pharmacies these patients also have to purchase them (and pay out-of-pocket) in community pharmacies. The latter group often has insufficient funds to buy medicines whose cost has a significant burden in the household budget of the poorest families.<sup>57</sup> Not surprisingly, Brazil's asymmetrical income distribution has led to unequal access to medical and pharmaceutical care (IBGE, 2000). Even if in recent years a decline in Brazil's social inequality was observed (Barros *et al.*, 2006), the country has one of the highest levels of income disparity in the world, as evidenced by the 2010 Census (Silva 2011). As an indication of social improvement, in 2011, the National Household Sample Survey (PNAD) showed a decrease in the Gini index<sup>58</sup> from 0.518 in 2009 to 0.501 in 2011 (IBGE 2013). Despite these developments in social indicators, the lack of access to medicines remains one of the main challenges to the public health system in Brazil (Portela 2010).

SUS' failure in providing sufficient medicines to users, among other factors, could be ascribed to the late development of public pharmaceutical assistance. There was a ten-year gap between the establishment of the National Health System (SUS) in 1988, and the inclusion of pharmaceutical assistance on the federal government's agenda. It was in 1998 that, in line with health reform, the National Medicines Policy (NMP) decentralised the management of the basic pharmaceutical

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<sup>57</sup> In the poorest households, the share of drug spending in total household monthly expenses represented 4.2%. For more details see Chapter two, section 2.5.3- Private expenditure on medicines.

<sup>58</sup> The Gini coefficient or index measures the inequality among values of a frequency distribution (for example levels of income). A Gini coefficient of zero expresses perfect equality (for example, where everyone has an exactly equal income). A Gini coefficient of one expresses maximal inequality among values (for example where only one person has all the income). Source: US Census Bureau. *Current Population Survey (CPS) - Definitions and Explanations*; available at <http://www.census.gov/cps/about/cpsdef.html> [last accessed 20/07/2013]

assistance to municipalities or states. Decentralisation was the strategy chosen to solve the shortage of basic medicines experienced by municipalities. The process of decentralisation re-distributed power, funds and responsibilities, which in turn enabled local authorities to match the provision of medicines to their specific needs. In January 1999, a ministerial ordinance has made states and municipalities responsible for the purchase and distribution of basic medication (Ministerio da Saude, 2000b). Funding to purchase medication for primary care, however, was sent to municipalities only from 2005, when decentralised supply actually started.

Funding for the NMP, like all other health care activities, is shared between the three levels of the federation. The Ministry of Health plays a major part in the co-funding of the health system, being responsible for half of the resources. It means that the implementation of policies by sub-national levels is heavily dependent on funding from the federal government. According to Arretche and Marques (2007), this system of redistributive transfers of resources allowed the widespread provision of basic health services by municipalities, but did not mitigate regional differences in the standard of health services, which still occur.

Responding to the failure in provision of medicines, the budget of the Ministry of Health regarding pharmaceutical assistance has increased considerably in recent years. The federal government's drug expenditure increased 144% between 2003 and 2007. Additionally, the expenses with medicines in relation to the total federal investment in health rose from 5.4% to 11% between 2002 and 2004 (Vieira and Mendes, 2007). Despite this steady growth in federal government expenditures, a national household survey conducted in 2008 revealed that in the poorest households about 76% of the total spending on health was spent on drugs (IBGE, 2010). This is an important issue, as the lack of access to free of charge medicines means high expenses for the poorest individuals, jeopardizing their basic needs. The high cost of medicines also leads to failure in following the recommended treatment, which, in a vicious cycle, hinders their health recovery. In 1999, it was estimated that 40% of the Brazilian population could not afford to purchase drugs at community pharmacies, and the only alternative was to obtain their prescribed drugs free of charge from pharmacies in the governmental primary care network (Callegari, 2000). This high proportion of the population relying exclusively on SUS to obtain their prescribed medicines emphasizes the importance of public provision in Brazil.

Decentralisation, as one of the pillars of SUS, has been much studied and debated in Brazil, focusing mainly on its positive aspects and its need for implementation. However, there are no extensive studies on the difficulties entailed in decentralisation, especially with regard to the

national medicines policy, pharmaceutical assistance and access to medicines. In this chapter, I will shed some light on this discussion, analysing how decentralisation of pharmaceutical assistance developed, who the main actors are, and the rationales that guided the process. The chapter has six sections, in addition to this introduction. The first section discusses the roles and motivations of sub-national actors in the decentralisation process. The changes introduced by the National Medicines Policy in the basic pharmaceutical assistance are discussed in the second section. The third section analyses how decentralisation was conducted. The regional differences that shaped decentralisation are discussed in the fourth section. The fifth section discusses sub-national experiences enabled by decentralisation. Lastly, before reaching conclusions, the limits of decentralisation or centralisation perceived by the interviewees are the subject of analysis in the sixth section.

#### **4.2 Call for changes in basic pharmaceutical assistance: the main actors and the motivations**

In the centralised model of pharmaceutical assistance managed by the Ministry of Health, all municipalities used to receive the same set of medicines, independent of the epidemiological profile of the region. A country as large as Brazil shows a wide variation in disease incidence and prevalence when comparing regions from north to south. As expected, this dissimilarity is translated into differences in needs for medicines. Acquisition of medicines tuned both by local necessities in terms of quantity, and by epidemiological characteristics, was amongst the main motivations for health secretaries to push for decentralisation. In general, interviewees highlighted the unsuccessful strategy to supply medicines adopted by the Ministry of Health. The amount of medication sent was not calculated in accordance with the demand from each municipality, leading to a lack of some drugs and wastage of others. The inadequacy of the model is summed up by this participant:

*When provision of medicines was centralised at the federal government, drugs often did not arrive on time in the municipality. These medicines were distributed uniformly throughout the country, without regard to regional differences. What Amazonas needs, Minas Gerais does not use... but for many years we have received these same drugs, which in many cases remained on the shelf until the expiry date and we had to throw them away (Interviewee 6;5.1).<sup>59</sup>*

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<sup>59</sup> Amazonas (North region) and Minas Gerais (Southeast region) are states of the federation. Amazonas is less urbanised and has a lower ageing index (16.6%) when compared to the Southeast region (40.8%). The ageing index is the number of over-60-year-old inhabitants divided per 100 under 15-year-old inhabitants in a

Difficulties in logistics to distribute the drugs around an extensive country such as Brazil were another intrinsic characteristic that is believed to have contributed to the failure of the centralised model of drug provision. The interviewees argued that as the acquisition was centralised, problems in the procurement process and delays in the distribution had the potential to affect a wide range of municipalities or even the whole country. The coordination of the whole process of planning the purchase, conducting a national procurement process, and delivering the medicines on time and in appropriate amounts to each region, had multiple critical points which affected the provision of medicines.

After experiencing frequent failures in the supply of essential medicines, municipalities considered that the autonomy to decide when and which drugs to buy could be the solution to access issues. And, in fact, in my interviews with sub-national actors, it became apparent that their narratives reinforce the idea that the support given to the implementation of the decentralised model was based on the expectations that this sort of problem could be overcome.

The National Council of Municipal and State Health Secretaries, CONASEMS and CONASS respectively, in which health secretaries of all Brazilian regions participate, were instrumental to bring together the voices of dissatisfaction with the existing lack of consistency within the policy of drug provision. The health secretaries claimed that, although they were responsible for local primary care, they did not manage a crucial element within the process: the provision of essential medicines. They argued that failures in medicine provision were preventing the fulfilment of patients' needs and putting local authorities in a bad position within the community. Some of the municipal authorities interviewed used a common expression that illustrated their urgent need to solve the shortage of medicines, which could be summarised as: *Citizens knock at the municipal health secretary's door, not at the Ministry's door, when asking for medicines. They live in the municipality, not in the state or in the Union (Interview 1; 13.1).*

The decentralisation of primary care brought the issue of drug shortages to the agenda of the state and municipal health secretaries. My interviewees suggest that provision of basic medicines gained

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specific area. The infant mortality rate in 2004, in the North, was 25.5 compared to 14.9 in the Southeast region. Infant mortality rate is the number of deaths of babies under one year of age per 1,000 live births in a specific area in a year (REDE Interagencial de informacoes para a Saude-Ripsa, 2008). These demographics are translated into differences in epidemiology and therefore differences in medicines needed to treat the most prevalent diseases in each region.

importance for municipal health secretaries when decentralisation of primary care took place in the 1990's. At this point, municipalities became responsible for health care delivery, which is intrinsically linked to medicine provision, given that medication is part of almost all health treatments. This need increased the awareness of health secretaries, especially at municipal level, of the importance of having control over the purchase and distribution of medicines. At the same time, the Ministry of Health also resented the difficulties in running the centralised process of drug provision, as illustrated in this quotation:

*It was a mix of the dissatisfaction voiced by CONASEMS and CONASS that the drugs did not arrive, but was also dissatisfaction on the part of the Ministry of Health, because we were running things here without being able to plan, purchase and deliver the drugs on time. Imagine making a bid for the supplier to deliver all over Brazil. In some cases it was impossible. It was an inefficient policy. This centralised process could not deliver the drugs in the way we needed. So, there was dissatisfaction and criticism in the municipality and in the state, and internal dissatisfaction [among Ministry of Health officials at the federal level]. The outcome was: how much is spent on that? X is spent, so take that X and transfer [it] to the municipality and state and they will manage the supply locally (Interview 13; 5.1).*

From this quotation we can see that while the push for decentralisation might have been led by state and municipal health secretaries, their demands for change found strong echoes within the Ministry of Health. Another aspect that we can explore in this quotation is the association of decentralisation with funding. To the Ministry of Health, to decentralise meant simply to distribute money, as that interviewee stated. I shall return shortly to what decentralisation meant to federal and subnational levels, in section 4.7.

Although subnational actors called for changes in the management of basic medicine provision, the interviewees, in general, portrayed decentralisation of basic pharmaceutical assistance as an expected development within the decentralisation of primary care. In their accounts, the distribution of responsibilities to municipalities was portrayed as an incremental development of the health system. For state and municipal health secretaries the provision of basic medicines should be managed at the local level, as primary care was. This view was plainly and simply expressed by this state health secretary:

*I really think that the right strategy was to decentralise the pharmaceutical assistance (Interviewee 2; 2.1).*

The changes brought about by the pharmaceutical assistance policy are also seen as a natural consequence of the decentralisation process undertaken by the health reform that created SUS. Interviewees generally felt that as decentralisation is a pillar of SUS, the competencies to manage the basic pharmaceutical assistance would, certainly, be decentralised and it was only a matter of time. When asked about the motivation to decentralise pharmaceutical assistance, one state health secretary replied:

*In fact, decentralisation is one of the guiding principles of the system's organisation and results in a motto, not only for the pharmaceutical assistance but for all areas of SUS. (...) The decentralisation of pharmaceutical assistance followed the process of primary care decentralisation and municipal accountability [for primary care]; those are things that are intertwined. I understand that it is not possible to think of organizing [at municipal level] primary care without organizing pharmaceutical assistance. I see the decentralisation of pharmaceutical assistance as a consequence of primary care decentralisation (Interview 6; 4.1).*

My interviewees suggested that, as the decentralisation of health services was already in place as a result of the implementation of SUS, the distribution of power and responsibilities for pharmaceutical assistance was an expected development of these wider reforms that started in 1988. When asked what led to the decentralisation of basic pharmaceutical assistance, one state health secretary, a member of CONASS and CIT, argued:

*I think, first, it was to complete the autonomy of the municipality. It does not make sense to keep pharmaceutical assistance centralised when the rest of the health policy was decentralised, and even municipalised. In addition, of course it was [decentralised] to promote greater access. And so, municipalities had more participation in the negotiations about health policy. I think it happened in the pharmaceutical assistance as well as in other areas. One of the pillars of SUS is exactly decentralisation (Interviewee 2; 8.1).*

From this quotation we can see the association of decentralisation with a wider municipal autonomy. As illustrated by the quotation, it was expected that decentralisation would bring improvement to the access to essential medicines and, hence, to primary care, which was already under municipal rule. The next section will explore one of the most important pieces of regulation involved in the decentralisation of basic pharmaceutical assistance.

### **4.3 National Medicines Policy introduced important changes in the basic pharmaceutical assistance**

The necessity of reorganising and integrating pharmaceutical assistance into SUS activities, added to the precarious supply of basic medicines, contributed decisively to the development of a new framework in 1998: the National Medicines Policy. The new policy provided the bases for the decentralisation of pharmaceutical assistance, enacting the changes demanded by subnational actors. The NMP was approved by the Tripartite Intergovernmental Commission (CIT) and the National Health Council (CNS) and was later complemented by the National Pharmaceutical Assistance Policy (NPAP) (Ministerio da Saude, 2001).<sup>60</sup> The development of this national policy is seen by interviewees as a significant measure which placed pharmaceutical assistance in a better position within the SUS policy hierarchy.

Implementation of the NMP started at the beginning of 1999. It was a bold initiative that introduced a set of guidelines to cover a broad scope of principles and actions, which included decentralisation and effective adoption of RENAME<sup>61</sup> as the mandatory guideline for medicines to be distributed by SUS, promoting their rational use. The new policy adopted a systemic and multidisciplinary perspective on Pharmaceutical Assistance, which was to be followed by all regions. The purposes and guidelines established by the NMP, whose scope goes beyond the acquisition and delivery of medicines, required significant work and involved close partnership between government levels.<sup>62</sup> I will return to these governmental relations entailed in decentralised pharmaceutical assistance in Chapter Five.

The directive of the NMP that is linked directly to the present study involves the reorganisation of pharmaceutical assistance, which redefined the tasks and powers of the three levels of management. The main criticisms of and complaints about the centralised management of medicine provision were acknowledged by the federal government when the policy was presented. Concerning this initiative, the federal government prioritised the decentralisation of the acquisition and distribution of drugs. This meant that the purchase and distribution of basic pharmaceutical

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<sup>60</sup> The context and actors involved in the creation of NMP and NPAP was discussed in Chapter One, section 1.4.

<sup>61</sup> RENAME is the *Relação Nacional de Medicamentos Essenciais* or National List of Essential Medicines

<sup>62</sup> The NMP established eight guidelines: adoption of the National List of Essential Medicines – RENAME; sanitary regulation of medicines; reorientation of pharmaceutical assistance and promotion of rational use of medicines; scientific and technological development fostering the production of medicines; and development and training of human resources.

components by the Ministry of Health would be replaced by regular and automatic transfers of federal resources, in the form of a supplementary incentive named Basic Pharmaceutical Assistance Incentive (IAFB – *Incentivo à Assistência Farmacêutica Básica*). Municipalities, coordinated at the state level, should use these funds to purchase medicines required for primary health care. According to the NMP, the state would receive technical cooperation from the federal level to coordinate the process, thus ensuring that medicines were bought in accordance with the epidemiological situation of each municipality. The state level coordination was also aimed to ensure municipalities would use appropriate prescribing and dispensing routines. According to the NMP, pharmaceutical assistance would encompass activities of selection, programming, acquisition, storage and distribution, quality control and use - prescription and dispensation - favouring permanent availability of medicines according to the needs of the population, with the identification of needs based on epidemiological criteria. In order to fulfil their new responsibilities, the municipalities needed to train and qualify human resources and invest in pharmacies' infrastructure and storage facilities.

Although the policy provided scope for profound changes, including initiatives beyond the acquisition and distribution of drugs, the incentive provided at first could only be used to purchase drugs for primary care. This mismatch between more comprehensive municipal tasks and the lack of funding to enable all these specific goals limited the implementation of that policy, as will be discussed in detail in Chapter Six.

My interviewees expressed their satisfaction with the fact that pharmaceutical assistance had reached a higher status on the SUS agenda, evolving from being a federal programme, which distributed standardised sets of basic medicines to municipalities, to becoming a national policy whose scope goes beyond the simple dispensation of drugs.<sup>63</sup> In the following quote, the interviewee recognises that the field has room for improvement, while emphasising the importance of having a policy to lead the development of pharmaceutical assistance within SUS:

*It was a great achievement, the level of organisation that pharmaceutical assistance has today, of course it has a lot to improve with respect to high-cost medications, for example, but that is another story...but getting [the management of] the basic pharmaceutical assistance [after decentralisation], this was a process that empowered the municipalities and invested the sector with a pharmaceutical assistance policy. It is no longer just a programme to dispense medicines. It has received another connotation, which provides*

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<sup>63</sup> Before the decentralisation of the pharmaceutical assistance the distribution of basic medicines was made by the federal Basic Pharmacy Programme.

*completeness of attention and enables access to drugs as an important tool towards comprehensive [health] care (Interviewee 4; 13.1).*

This interviewee, a state health secretary, reported advances in organisational aspects of the decentralisation process. From his quote we can also see the association of decentralisation and the NMP with the empowerment of municipalities. The idea was that the redistribution of power entailed in the decentralisation would allow municipalities to organise the pharmaceutical assistance focused on the provision of medication to treat people living in the area. It meant that municipal managers could choose which medicines to buy, the quantity needed, and how to dispense them. The advances in the field, however, proved that more than just changing national policies toward municipalities would be necessary for the management of the comprehensive cycle of tasks involved in pharmaceutical assistance.<sup>64</sup> In fact, the NMP was enacted in 1998, but in practice the management of drug provision by municipalities only occurred after 2004<sup>65</sup>. So, immediately after the NMP came out, no changes in terms of medicine provision could be observed by SUS users.

This delay in implementing the actions provided in the NMP is better understood if we consider the global health context. The World Health Organisation (WHO) guidelines on national pharmaceutical policy, which informed the design of the NMP, were first published in 1988. Although these guidelines included concerns with essential medicines and access, it was only in 2004 that the WHO established a new strategy based on key objectives for improving access to essential medicines and strengthening the national medicines policy (WHO, 2004). So, even though there were internal motivations for the entry of pharmaceutical assistance in SUS agenda, the move followed the timing established by the WHO. Although the interviewees argued about the importance of municipal and state demands to trigger the process of decentralisation of provision, the circumstances suggest that changes took place in accordance with the international context. After this note on the wider context related to the introduction of the NMP, the next section will explore how the negotiations for decentralisation developed.

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<sup>64</sup> The Pharmaceutical Assistance Cycle consists of drug selection, procurement, storage, distribution and dispensing, monitoring, evaluation and supervision of pharmaceutical activities.

<sup>65</sup> A detailed view of the timeline of actions regarding the distribution of power and responsibilities to state and municipal level is shown in Appendix 2. In 2005 decentralisation began for the acquisition of 55 drugs for different health programmes. However, the purchase of medicines for diabetes and hypertension was still centralised in the Ministry of Health.

#### 4.4 Decentralisation of pharmaceutical assistance: a negotiated process

Although decentralisation of the management of pharmaceutical assistance has been provided in the NMP since 1998, it was only from 2005 that this process really began to take shape at the municipal level. The circumstances explaining this delay between the enactment of the NMP and its implementation are illustrated by a municipal health secretary in this quote:

*So, I think that, actually, the legal framework of SUS was much more advanced than the concrete foundations to implement what was already provided in the legal framework. Thus, much of what actually is in the 1988 Constitution and the 8080 Act [SUS Organic Act enacted in 1990], took five, ten, twenty years to start to be part of the political agenda of SUS. There was a gap between what was placed in the legal framework and the actual conditions we had to make it happen. So, those things started to appear on the political agenda only when the actors, and the country, had the energy to do it. So I believe that Pharmaceutical Assistance had this same trajectory ... There was a time when it was politically possible to build the National Pharmaceutical Assistance Policy, discuss the tripartite funding, the components in the organisation of Pharmaceutical Assistance: basic, strategic and specialised. All of these ended up being in tune with the broader policy discussion of the SUS (interviewee 8; 3.1).*

The aspects evoked by the interviewee in order to explain how decentralisation of pharmaceutical assistance entered the political agenda shed light on an important characteristic related to SUS legal framework. This assessment that the legal framework was very advanced compared to what could actually be done is not only a shared vision among my interviewees but also among scholars in this field. This mismatch could lead the actors to not question the slow development of the various areas of SUS. In my view, the actors showed a certain degree of complacency because what was expected in terms of care and access is so far beyond what it is possible to achieve that they knew in advance that the target would be missed. From another perspective, the legal framework created high expectations in relation to SUS performance, which were not frequently met, leading to a general perception of failure. SUS, in theory, should provide universal access to any level of health treatment and medicines, which is certainly not true.

Decentralisation of the management of pharmaceutical assistance is portrayed by most of my interviewees as a gradual and negotiated process. The narratives suggest that the negotiations involved the three government levels and were coordinated by the federal level. Additionally, the changes in pharmaceutical assistance were preceded by other decentralised experiments that took place in health care. In certain aspects these experiments conferred legitimacy on the municipal

health secretaries to demand for more power to manage medicine provision, as articulated by this interviewee:

*The decentralisation of 2005 did not occur unilaterally. Within SUS this is not allowed. So, there was an evaluation of states and municipalities, which was also shared by the Ministry of Health, that the drugs for basic pharmaceutical assistance did not always reach their destination. There were millions of pills [to be purchased], in a logistics system that did not work, procurements that did not work. So the municipalities did not buy [drugs], they kept waiting [for purchases by the Ministry of Health] and when they got [the drugs] the amount was exaggerated. So the planning was deficient. Thus, it was agreed, we agreed, to decentralise (...) that was not a unilateral process; it had to reach a consensus. This agreement had to arrive at a consensus. So it happens that way. Is the subject mature enough to experience another type of arrangement? (Interviewee 13; 3.1)*

This concept of level of maturity voiced by the above interviewee encapsulates the incremental nature of the process of changes brought about by decentralisation. A recurrent argument expressed by many interviewees relates to the very nature of SUS and its agreement process. Empowered by the municipalisation of health care, municipal health secretaries pushed for more autonomy. They wanted to manage the provision of medicine within the municipal health system. They asked for autonomy to decide which medicines to buy and for funds to make these purchases. Following the steps of the policy-making process implemented by SUS, municipal demands reached the state level forums of negotiation (COSEMS and CIB).<sup>66</sup> These municipal demands found echoes within the Ministry of Health. Overall, the interviewees share the view that the process culminated in an agreement, and decentralisation was presented as the solution to the inefficiencies of the centralised model. The regional differences and the continental dimensions of the country were used to explain the inappropriate catalogue of drugs provided by the federal government and the difficulties in distribution.

One Ministry of Health official, however, expressed a dissonant view about the idea that decentralisation could be an adequate response to the provision issues and also disagreed that the process of change was as smooth as portrayed. This interviewee expressed doubts about the suitability of transferring responsibilities to small municipalities to manage the supply of medicines. Also, the interviewee suggested that the changes introduced by the decentralisation

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<sup>66</sup> COSEMS- Council of Municipal Health Secretaries. Each state has a COSEMS which brings together all municipal health secretaries within the state. COSEMS participates in the CIB- Bipartite Intergovernmental Commission (state and municipalities).

process did not always happen in tune with the timing of the municipality. This informant argued that some municipalities were practically forced to take responsibility for tasks that they were not prepared to carry out. In these cases, state health secretaries did not give municipalities the option of having the provision of medicines managed at the state level. This interviewee argues that even today these municipalities still do not have the administrative capacity and infrastructure to provide access to basic medicines in their jurisdiction, as summed up in the following quotation:

*So I think that decentralisation was a little forced and perhaps even today, some municipalities are not prepared to assume this responsibility (Interviewee 19; 1.2).*

This theme of municipalities being unprepared to take over the management of pharmaceutical assistance, although not so clearly expressed as in this quotation, is present in a significant number of the interviews conducted. At this point it is necessary to explore further what it means to be 'unprepared', according to the views voiced throughout the interviews.

On some occasions, being prepared was related to being organised and having sufficient and qualified human resources as well as infrastructure. In this case, interviewees from subnational tiers argued that adequate federal funding, technical support and political will could solve the issue of unpreparedness, creating a favourable environment for the implementation of decentralised functions. Another line of reasoning relates the lack of prepare to limitations inherent to small municipalities<sup>67</sup>. This line argues that the limited administrative structure, characteristic of small municipalities, makes it difficult to carry out decentralised tasks. The alternatives, as pointed out by proponents, were to rely on the state level for technical support and also to substitute the federal level in the purchase and distribution of essential medicines, as was the case in the previous centralised model. This optional arrangement was made explicit in the NMP. Decentralisation was not compulsory, so municipalities could, in theory, choose to receive medicines bought by the state level instead of being funded directly to purchase those drugs. In some states that was the option taken by many municipalities, as for example in São Paulo and Paraná, matters to which I shall return in section 4.6. But, as we will discuss in the following section, some municipalities did not have the alternative of opting out of decentralisation and had to take on the provision of basic medicines even without suitable infrastructure or resources.

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<sup>67</sup> In Brazil 70% of the 5,565 municipalities have fewer than 20,000 inhabitants in comparison with some that have several million. Source: IBGE Censo Demografico 2010, available at:<http://www.ibge.gov.br/home/presidencia/noticias/imprensa/ppts/0000000402.pdf> [last accessed 20/07/2013].

#### **4.5 Regional differences shaping the implementation process**

As one might expect, the implementation of decentralisation in the public provision of medicines did not follow the same pace throughout the country, and some informants even consider that decentralisation is not yet complete. Among the elements that participated in policy-making, the concept of decentralisation is seen by interviewees as something that could take on distinctive features, depending on the available infrastructure and context of the municipalities or states involved. These differences include, for example, having human resources to manage the procurement processes and public laboratories to produce essential medicines in the state.

Arretche and Marques (2007) are among the scholars who argue that the main focus of the federal government has been the promotion of decentralisation in itself, and that less effort has been placed in initiatives to reduce inequalities. Corroborating this argument, studies conducted to evaluate the implementation of decentralisation of health care in two geographical areas in Brazil argued that decentralisation in itself does not ensure changes in the standards of municipal health systems (Vieira-da-Silva *et al.*, 2007; Atkinson and Haran, 2004). Decentralisation in the management of basic pharmaceutical assistance did not happen to the same extent in all Brazilian states and municipalities. Although regional differences were a motivation for decentralisation, these same differences proved to be a limitation to the process. According to my interviews, the lack of infrastructure in small municipalities was a significant barrier that prevented some of the proposed changes from being implemented. These structural differences displayed by some regions resulted in differences in the level of decentralisation implemented. According to interviewees and policy documents some municipalities have chosen to exercise full control while others delegated the task of buying drugs to the state level. Within the more developed states in terms of health care facilities and administrative infrastructure, the state level of the management held the responsibility for purchasing and distributing essential medicines. Thus, in states that took the responsibility and centralised the procurement of essential drugs, the small municipalities had their lack of structure covered and could benefit from the distribution of power in terms of the decisions about what and how much to buy. However, in some circumstances, as we mentioned before, municipalities did not have the option to delegate and ended up with responsibility for the whole management. Municipalities located in less developed states, especially those with fewer than 20,000 inhabitants, struggled to meet the new responsibilities brought about by decentralisation of pharmaceutical assistance, without state level support. Some municipal health secretaries reported a precarious situation, in small municipalities, where they did not receive any support at the state level. As they

explained, this lack of support was not exclusively related to pharmaceutical assistance but affected the whole municipal health system.

With regard to the level of decentralisation implemented, until today there are basically two types or stages of decentralisation, depending on where the responsibilities and power are concentrated: municipal (complete decentralisation) or state (partial decentralisation). Regarding complete decentralisation, the municipal level receives the federal and state counterpart of the funds for basic pharmaceutical assistance – the IAFB - and is in charge of the whole process from planning to dispensing, including public tender. In partial decentralisation, federal and municipal funding counterparts are sent to the state which is responsible for planning – together with the municipalities - purchasing and distributing the medicines within the state.

These differences in administrative capacity combined with the existence, or not, of state level support worsen the disparities in pharmaceutical assistance offered by municipalities. Whereas in some regions some sophisticated forms of management for the public provision of medicines were put in place, like the consortium in Paraná state, other municipal managers do not even know that they have received funds to purchase medicines, as illustrated by this quotation:

*I think that decentralisation was an important process, but it was traumatic for some of the municipalities. Some states, like São Paulo, Minas Gerais, and Ceará centralised the acquisition because they have public pharmaceutical laboratories to produce those medicines. The municipalities within these states, I believe, have suffered less (...) Other states do not support the municipalities in the purchase, and the transfer [of federal funds] goes directly into the municipal fund, in this case what we observe is that they get [the money] and they do not even know it is for pharmaceutical assistance. So we had some managers that came here [to the Ministry of Health in Brasília] unaware that they have financial resources for basic pharmacy, or for any budget block [of financing in health care]. The money is deposited in that city and they did not know what they have to do with that resource. So, it is important to decentralise, but I think it has to be analysed better to avoid these inequities that may be happening (Interviewee 19; 1.3).*

In agreement with this discussion about inequalities among regions which affect decentralisation, CONASEMS emphasizes that the process of decentralisation has received funding that is incompatible with the responsibilities distributed to municipalities (CONASEMS, 2010). It further argues that there was a reduction in the state health secretariats' responsibilities in the healthcare

field. The reduction in the assistance role combined with the lack of clarity about the new rules to the state level is perceived by subnational actors as negative aspects of the decentralisation. This assessment that the state level saw its role reduced after decentralisation, and that municipalities were burdened, is a widespread complaint in Brazil. This matter of the state level role in pharmaceutical assistance will be discussed in more detail in Chapter Five. CONASEMS argues that the organisation of health care is based primarily on the provision of services and not on the needs of the population, which increases regional inequalities and difficulties in accessing the most vulnerable populations. Thus, the provision of services may be regarded as being directly linked to infrastructure, which is normally better in the more developed regions. In general, less developed regions do not have adequate infrastructure and frequently concentrate the most vulnerable population. This assessment is applicable to pharmaceutical assistance as well. Although it indicates that decentralisation may increase regional differences, from a different perspective, the policy-making process may be influenced by subnational successful experiences, as will be discussed in more detail in the following section.

#### **4.6 Bottom-up policy-making: subnational experiences informing national policies and initiatives**

Although the distribution of responsibilities posed many challenges, the participation of subnational actors in the decision-making process provided by decentralisation is highly valued by the interviewees. The most valued characteristic pointed by the participants belonging to state and local levels was what can be called bottom-up policy-making. These features were: freedom of choice of drugs most appropriate to local needs; federative forums of agreement; and the legal requirement to reach a consensus on the stances of agreement at the state and national levels (CIB and CIT).

Decentralisation and the consequent bottom-up policy-making enabled subnational initiatives to emerge in order to solve the usual problems in pharmaceutical assistance. This is one of the intrinsic values ascribed to decentralisation: to allow ideas generated at the municipal level to be used to solve national problems.

When participants were asked what they could identify as a subnational innovative initiative that could only have arisen in a decentralised context, they pointed out three significant innovative approaches from four different states of the country. The examples came from Paraná, São Paulo,

Bahia and Sergipe, states which have quite remarkable differences in terms of health infrastructure, economic development index, and demography.<sup>68</sup>

#### 4.6.1. The Paraná Consortium

The first innovation the interviewees ascribed to decentralisation came from Paraná, which was the first state to organise a medicines consortium. The initiative, according to two interviewees from Paraná, was put in place by the state health secretary in 1999. The Paraná Consortium is mentioned with enthusiasm as achieving consistent positive results over the years. I could confirm in a CIT meeting I was observing<sup>69</sup> that Paraná is presented as an example of state where access to essential medicines has been solved and the consortium is believed to be the main reason for this achievement. The consortium centralises the purchase of medicines and manages the financial resources, but the selection and planning are still a municipal responsibility.

Although municipal health secretaries valued the results achieved with this initiative, the autonomy to manage the basic pharmaceutical assistance has brought challenges, as one interviewee from Paraná state explained. Subnational levels had to find strategies to optimize the use of financial resources. The main concern was the management capacity of small municipalities, and the modest amounts of medicines to be purchased by small municipalities (about 80% of the municipalities in Paraná have less than 20,000 inhabitants). The strategy proposed by the state health secretariat was to create a consortium that centralised the purchase of medicines, whereas each municipality selected the medicines and their respective quantities. In 2011, about 97% of the municipalities of the state were part of the consortium which was cited by ten out of the 20 respondents as an example of a successful administrative strategy. Among the issues solved, it was pointed out that the consortium provided efficient management of medicines' procurement and rational use of financial resources, allowing wider access to medicines.<sup>70</sup> In line with this perception, Ferraes and Cordoni Junior (2007) remark that acquisition of medicines by the consortium costs on average 29.7% less than the prices set by federal standards. It is remarkable to find a subnational initiative which seems to be more cost-effective than a national procurement procedure. Against the

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<sup>68</sup> Sergipe: poverty incidence 47.80%; Gini index 0.50; Bahia: poverty incidence 43.47%; Gini index 0.49; Parana: poverty incidence 39%; Gini index 0.47. Source: IBGE; *Map of Poverty and Inequality – Brazilian Municipalities* 2003; available at <http://www.ibge.gov.br/estadosat/temas.php?sigla=ac&tema=mapapobreza2003> [last accessed 20/07/2013]

<sup>69</sup> CIT meeting on 26th October 2011 in Brasilia.

<sup>70</sup> 10 out of 20 interviewees talked about the consortium as a strategy to overcome decentralisation limitations; four of them used the Parana Consortium as a successful example.

economic odds, which according to the economies of scale would predict better prices in a national purchase, decentralisation in this case proved the contrary.

According to the interviewees, the consortium was responsible for raising the awareness of municipalities in Paraná about the need for investment in human resources to organise pharmaceutical assistance and to face the challenges of selecting and planning for purchase of medicines. The interviewees' perception is that, as the issues of purchasing were solved by the consortium, municipal health secretaries had the opportunity and the motivation to tackle other aspects involved in the provision of medicines. Consistency in the distribution of basic medicines provided by the consortium unburdened municipal health secretaries to focus on hiring and training human resources to select and distribute medicines according to local needs. The importance of this pioneering initiative is summed up by this participant:

*It is pioneering in Brazil; Paraná was one of the first states of the federation to work in the form of consortia of municipalities.... It was the first involving medicines. Of course, throughout these 12 years it has been improved. And it has advanced, has expanded the list of medicines and systematically has increased the participation of the municipalities. .... All this was set within the CIB<sup>71</sup> and what we have today is a strategy that has been very well resolved by the municipalities in relation to primary care medicines. The price... according to the bank of prices [database] of the Ministry of Health, for more than 10 years the consortium is the public institution that buys drugs cheaper.... It organized the purchase, so the municipalities were aware that they needed to have professionals, especially pharmacists, to organise the programming, and the planning (Interviewee 3; 1.6).*

Along with the emphasis that the interviewee places on the positive aspects of the consortium the narrative also suggests that pharmaceutical assistance in Paraná reached a superior standard when compared to the Brazilian situation. The management of basic pharmaceutical assistance at state level, according to the interviewee, resulted in many financial and operational benefits. Aided by the consortium, municipalities invested efforts in expanding the list of drugs and pharmaceutical services delivered because they had money and professionals available.

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<sup>71</sup> CIB is the Bipartite Intergovernmental Commission

#### **4.6.2. *MEDCASA* in São Paulo and *Remédio em Casa* in Bahia<sup>72</sup>**

The second innovative approach developed to improve access was the delivery of medicines by post directly to the patient's address. Currently two states use this strategy to provide medicines: Bahia has the programme *MEDCASA* and São Paulo has *Remédio em Casa*, which was implemented in the state capital and in other cities within the state.

The *Remédio em Casa* programme was put into practice by the Municipal Health Secretariat of the city of São Paulo. The programme delivers medicines to treat patients with chronic diseases for the period of 90 days. Patients should be clinically stable, and being assisted by SUS to qualify for the programme. *Remédio em Casa* was implemented in 2005 initially with medications for diabetes and hypertension and was gradually expanded to cover other chronic conditions such as dyslipidemia and hypothyroidism.

*MEDCASA* was an initiative launched in 2008 by the state health secretary of Bahia, to pay off an important financial debt the state had with the municipalities. The debt, as explained by one of the interviewees, was the contribution due from the state for pharmaceutical assistance that had not been sent to municipalities for years in a row. Two respondents from Bahia pointed out COSEMS' constant pressure as an important backing to the success of the municipalities' requests. The way Bahia chose to pay off the debt was to send drugs to treat diabetes and hypertension, by mail, to patients in treatment in the municipalities. My interviewee associates *MEDCASA* with improvement in pharmaceutical assistance, because the programme combines the distribution of medicines with health care, as patients should be in treatment at a municipal health unit to be eligible to receive home delivery of medicines.

#### **4.6.3. Sergipe's experience in regulating access**

The third innovative approach came from Sergipe, which in the 2000's, was the first to enact laws to regulate the operation of SUS at the state level with regard to the coverage of services and drugs. Sergipe was also the first to establish contracts to regulate the responsibilities of the state and municipalities. Among the tools created by Sergipe for managing SUS, the Standard of Coverage stands out, which contains: a list of services and medicines to be offered; the Guidelines for construction of the Health Map, which seeks to map and distribute the supply services throughout

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<sup>72</sup> *MEDCASA* merges the words medicines and home (MED+CASA), and *Remédio em Casa* means 'medicines at home'.

the territory; and the Public Action Contract, which defines what should be the responsibility of each governmental entity within state jurisdiction in the provision of health.

Those instruments implemented in Sergipe were introduced at the national level later on in 2011, with the enactment of Decree 7508 (Brasil, 2011). This is an example of how innovation and experimentation at state level have led to new policy measures that had broad national application, as illustrated in the next quotation:

*Historically in my state we've had a very interesting advance. The state of Sergipe experienced the changes which are now being discussed with Decree 7508 for Brazil. In Sergipe, we already have a contractual relationship between the state and municipalities defining the responsibilities of each one. We've also set a standard of coverage, and a standard of inputs, be they medicines, health products or devices. This greatly facilitates the relationship with the municipalities (Interviewee 5; 1.2).*

Although the new legal framework is portrayed by the interviewee as an advance in pharmaceutical care, this innovation can also be regarded as a response to restrain the tendency to turn drug dispensing into a judicial issue, which occurs in Brazil and is known as 'judicialisation'. It refers to a phenomenon in which patients take the government to court to gain access to health services and resources (in this particular case the term refers to lawsuits for access to medicines). In fact, the national decree that the interviewee refers to actually limits the provision of medicines to those listed in RENAME and/or in SUS Therapeutic Protocols. This was justified by the need to contain the financial impacts of supplying the high-cost drugs that are mostly involved in lawsuits. I will return to the judicialisation issue later on.

These three examples indicate the emergence of subnational alternatives to overcome issues raised by decentralisation in Brazil. They are in accordance with the idea that decentralised governments are more favourable to policy innovations and experimentation, as remarked by Oates (1999) and Osborne (1993:253). However, the innovative consortium strategy created in Paraná, in my view, is more likely to be a result of the autonomy intrinsic to federal states than of the decentralisation of pharmaceutical assistance. Assigning responsibilities relating to the governance of medicine provision to states and municipalities could, in a way, push the states to search for alternatives. Considering the circumstances, the innovative initiative of the Consortium was probably not the result of the decentralisation of pharmaceutical services per se, but, more likely, of the political and fiscal decentralisation that happened before the administrative decentralisation of health. The fact

that the Consortium was created in 1999, i.e. at a time prior to the effective implementation of decentralised basic pharmaceutical assistance, helps to explain my view. The same argument is supported by the fact that São Paulo, Paraná and Minas Gerais were precursors for the Basic Pharmacy Programme implemented by the federal government in 2004.<sup>73</sup> This reiterates the fact that certain states of the federation possessed, before decentralisation of pharmaceutical services took place, sufficient infrastructure, resources and administrative capacity to implement strategies for the supply of drugs that later would serve as a model for other national initiatives. Nonetheless, it should also be remarked that judicialisation played an important role in shaping the legal framework.

Judicialisation may be regarded as a process that has been used and adapted to respond to different situations concerning both patients and SUS. Court cases that are supposed to be used in extreme cases have become a usual approach to obtain drugs, as this municipal health secretary from Santa Catarina state explains:

*Today, with the ease of judicialisation I've seen a judicialisation process even to [buy] shampoo (Interviewee 7; 5.1).*

Initially, the drugs that were part of those lawsuits were primarily for the treatment of HIV/AIDS. After 1999, there was a decrease in cases that required these drugs, and others emerged such as hepatitis C, hypertension, rheumatoid arthritis and diabetes (Borges and Ugá, 2009). Although these lawsuits are well known and have been reported widely by the press, there is no nationwide survey depicting number of court cases or proportion of access provided via court cases. Despite the difficulty in measuring the total costs of the lawsuits, it can be observed that expenditure on paying claims ordered by courts has increased significantly since 2003. Ministry of Health expenses with court cases demanding medicines went from R\$170 000, in 2003, to R\$ 250 million in 2011 (Advocacia Geral da União, 2011). It is worth noting that the judiciary, as well as the health system, is also decentralised, so that the lawsuits are divided between the Federal Court and the Courts of each State, making it difficult to draw a national picture. However, a report by the legal consulting area of the Ministry of Health showed that about R\$ 950 million was spent on the lawsuits in 2010 by the federal government and eight of the 27 states.<sup>74</sup> This represented about 14% of total expenditure by the Ministry of Health on medicines to address all SUS users.

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<sup>73</sup> Basic Pharmacy Programme was the federal initiative which distributed standardised sets of basic medicines to municipalities before decentralisation of pharmaceutical assistance.

<sup>74</sup> Spending on lawsuits by 19 out of 27 states and all municipalities are not included in this sum.

As in other aspects of pharmaceutical assistance that I have already discussed, the role of medical doctors is important to understand the phenomenon of judicialisation. Lima (2009:54) has shown that doctors have been the first to direct patients' search for medicines through the courts. The author interviewed patients in Manaus and these patients reported that the doctor told them that if they could not find the prescribed medication in SUS facilities then they should use the judicial process. This behaviour illustrates how these professionals influence the implementation and performance of SUS pharmaceutical assistance. Taking this in conjunction with the prescription of drugs that are not part of the RENAME list, as reported by my interviewees, resulted in important factors that undermined the implementation of pharmaceutical assistance. Although this is an issue that has a profound financial impact on the whole health system, influencing the availability of medicines, as far as I am concerned these behaviours have not been discussed by the health secretaries. The next section will discuss what interviewees have explicitly reported as important factors that limited decentralisation.

#### **4.7 Partial decentralisation, complete decentralisation and centralisation: what are the limits perceived by the interviewees?**

Overall decentralisation is portrayed by the interviewees as a negotiated and gradual process which has not yet reached its full potential. In general, among the municipal and state health secretaries interviewed, the view is that basic pharmaceutical assistance decentralisation is a one-way process, i.e. the policy initiatives, and their financing strategy, are directed to distribute more power from the federal level to subnational levels, mainly municipalities. On the one hand, even when interviewees representing state and municipalities are directly asked and prompted with examples of centralised initiatives in the field – the Popular Pharmacy Programme, for instance - they tend to argue that it is not a move towards centralisation, given that municipalities still hold the same responsibilities and funding to provide basic medicines. On the other hand, Ministry of Health officials can more openly discuss the centralising aspects of these initiatives and, moreover, justify them. These findings regarding different views between subnational and federal actors are in close agreement with some of the conclusions of Exworthy *et al.* (2010), who investigated the inter-relationship between decentralisation and performance in the local health economy in the NHS in the UK. The authors argued that “decentralisation and centralisation usually exist together and policy attention on decentralisation can mask the centralisation taking place” (Exworthy *et al.*, 2010: 8).

One Ministry of Health official that played a key role in the decentralisation of pharmaceutical assistance argued that the process was focused on the transfer of federal funds to subnational tiers to finance the purchase of medicines. At the beginning of the process, from 2004 to 2006, as this interviewee explained, the focal point was: who has the money to purchase the drugs? At that time, when Ministry of Health officials referred to decentralisation, they meant distribution of funds to buy medicines. The NMP, however, had made it clear that decentralisation encompassed the management of pharmaceutical assistance beyond the purchase of drugs. Elaborating the idea of a restricted concept of decentralisation adopted at that time, this interviewee describes that, at the beginning, municipal health secretaries kept buying the same list of medicines they used to receive from federal level, as summed up in this quotation:

*But at first the discussion on decentralisation was: who buys [the medicines], who has the money in hand to buy. In reality in our view [the Ministry of Health's perspective], decentralisation should include the management as a whole. In other words, whoever is taking the important decisions at the local level related to the health system should also be able to make the decisions about which drugs were important, and how to accommodate local demands of medicines, and should, of course, have the money to do it. But the process was not so simple, so that even today it has not been totally solved yet (...) but when I was the director, decentralisation was closely tied to the concept of who has the money to manage the purchase of medicines. In fact, the list of medicines was not him [sic, the municipal health secretary] who had defined or decided on (Interviewee 18; 1.1).*

Alongside this observation that decentralisation was seen just as distribution of funds, this quotation also gives an idea about the gap between what was provided by the legal framework and what the municipalities actually could perform. The quotation presents a nuanced portrait of the municipal circumstances after decentralisation. If on the one hand their demands for autonomy were met, on the other hand, decentralisation has brought out the need to have the capacity and structure to manage pharmaceutical assistance.

But what are the actual difficulties in buying medicines? The motivation presented by municipalities to choose partial decentralisation was the gains of economy of scale and the bureaucratic difficulties inherent to the public procurements procedure, which requires highly skilled human resources. Awareness about the potential savings is widespread among the interviewees, both subnational health secretaries and Ministry of Health officials. Economies of scale in this case relate to better prices and consequently to the economy obtained by centralised

procurement by virtue of the larger amount of medicines purchased. The following quotation, from a municipal health secretary, illustrates this perception clearly:

*Municipalities that have centralised purchasing at the state level [i.e. partial decentralisation] have economies of scale. It is too complicated for a small municipality to buy small quantities of drugs; it will end up paying higher prices. The state will buy for a large number of municipalities and will get a better price. But when the state fails to buy certain drugs, especially hypertension, the municipality experiences shortages. The federal, state and municipal funding counterparts are committed in this process headed by the state [level]. If the purchase does not work well, these funding sources are no longer used to supply the population (Interviewee 10;1.4).*

This quotation also highlights the disadvantage most frequently cited by my informants: inconsistency in the distribution of medicines. Decentralisation that reached just the state level sometimes produces the same problems that motivated the decentralisation of pharmaceutical assistance in the first place. With this partial decentralisation, shortages were downsized from being a nationwide problem, when purchases were centralised in the federal government, to a regional scale. However, for municipal managers and patients, both approaches, in the case of failure, have the same consequences: shortage at the local level.

Regardless of the type of arrangement adopted, the regulatory framework mandates that the supply of basic medicines must be sorted out by means of a federative agreement between federal, state and municipal level, approved in the tripartite forum. Thus, in theory when the state fails to deliver medicines sanctions could be applied. But, in reality, some municipal health secretaries reported that when this agreement is breached there are no consequences for the state. Failure in fulfilling agreements and repercussions on access is a matter to which I shall return in Chapter Five.

Considering regional differences, it is worth noting that state administrative capacity and infrastructure, mainly regarding the public production of essential medicines by state laboratories, played an important role in the steps taken and in the extent of decentralisation experienced. Additionally, those features formed the context within which pharmaceutical assistance advanced. More developed states were able to accommodate and compensate the lack of managerial capacity and low volume of purchases in small municipalities. States from economically developed regions such as São Paulo and Paraná, for example, have centralised acquisition of medicines. In São Paulo, the *Dose Certa* programme was created by the state health secretary to manage the

acquisition and distribution of essential medicines for municipalities with fewer than 250,000 inhabitants.<sup>75</sup>

The programme is managed by FURP, the Foundation for Popular Medicines, the official pharmaceutical laboratory of São Paulo state, which is part of the São Paulo Health Secretariat. FURP is the largest public drug manufacturer in Brazil and one of the largest in Latin America. Although it could be expected that having such a public manufacturer would solve the main issues of medicine availability and costs, it is not currently the case. Some municipalities in São Paulo which opted for state management, are discontented with the sort of medicines distributed and their prices, and are now trying to opt out, as illustrated in this quotation:

*Today many of the 598 municipalities that are part of 'Dose Certa' have already realised that it's much more advantageous to opt out because the list [of drugs] is outdated, so now you have basically two standards of pharmaceutical assistance [within the state]. One in larger municipalities [that are not part of the Dose Certa Programme], which update their list and buy freely because they get the management at the Municipal Health Secretary (...) [and] we have a second standard of assistance in smaller and medium-sized municipalities, where it is not possible to use better medicines. But the worst is that several of these products which are produced by the FURP, when they are distributed the invoice shows that the drug is more expensive than the same drug bought directly by a small municipality with all the inconvenience of buying small quantities (Interviewee 1; 2.7).*

This quotation illustrates an inconvenience of decentralisation, which is often counted as an important disadvantage that arises from the distribution of power and resources: the inability to standardise the implementation of a given programme. From this quotation we can also see the discontentment of municipalities with state management of pharmaceutical assistance associated with inefficiencies of the public sector. The situation evidenced that distribution of medicines that involves the state level is problematic, even in São Paulo with its governmental pharmaceutical laboratory to produce medicines. This dissatisfaction, the interviewee suggests, can lead municipalities to demand complete control over pharmaceutical assistance.

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<sup>75</sup> *Dose Certa* means 'Right Dose'. It is the programme created by the state health secretariat in São Paulo to manage the acquisition and distribution of essential medicines to municipalities with fewer than 250,000 inhabitants. In Brazil only 2% of the municipalities have more than 250,000 inhabitants, and 54% have fewer than 10,000 inhabitants. São Paulo city is the biggest city in the country with 10,990 million inhabitants, but the smallest municipality with only 834 inhabitants is also in São Paulo state.

This perception of changeability in the level or extent of decentralisation has at least two perspectives. Firstly, municipal and state actors could use this to move forward or backward when it comes to responsibility for the complete management cycle. Secondly, the Ministry of Health interviewees suggest that this movement forward or backward in the extent of decentralisation could be used as an alternative to overcome operational and financing difficulties.

Overall, decentralisation is considered one of the pillars of the organisation of SUS and is passionately defended by its proponents. For the Ministry of Health, however, decentralisation or centralisation of basic pharmaceutical assistance is a changeable state that depends on the results achieved, as articulated by this Ministry of Health official:

*So, I think this process needs to have coherence. Decentralisation or centralisation must be in balance: what are the advantages and the disadvantages? In both processes, the Ministry of Health was right. It was right when decentralised and again it was right when, in 2009, it re-centralised the acquisition of some medication.<sup>76</sup> As Brazil is such a large and diverse country, we need always to evaluate whether it is good or not and if it should remain as it is. We also have to analyse if this arrangement [decentralised or centralised] is still appropriate. So, I think today we have to have that perspective, don't we? This movement of centralisation of some processes is to make savings, to gain scale (Interviewee 13; 2.3).*

Even if the centralised initiative exemplified in the preceding quotation does not refer to the basic pharmaceutical assistance which is the focus of my work, the example of cutting costs is used as striking evidence of the advantages of centralised bids. The justification of economies of scale is used once more to build the case for centralised initiatives. Certainly, the optimal level of delivering public goods and services varies with the tasks, as noted by De Vries (2000). Certain policies require technologies and involve economies of scale. Decentralised arrangements are more appropriate when there are fewer economies of scale involved (Tomaney *et al.*, 2011). When discussing the dangers of decentralisation, Prud'homme (1995:9) is categorical that “even the most decided decentralist acknowledges that services with economies of scale should not be decentralised.” I am going to explore the argument that the funds saved could have provided more medicines and improved access, as defended by the federal government, in Chapter Seven which explores the Popular Pharmacy Programme.

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<sup>76</sup> The interviewee is talking about the re-centralisation of planning, purchase and distribution of high-cost drugs, not essential drugs. Later on, the interviewee talked about the significant economy of scale as a result of this first centralised bid. Compared to the prices paid in the decentralised period, the first centralised bid cut around £80 million.

## **4.8 Conclusions**

As suggested by my interviewees, the decision of the Ministry of Health to decentralise the management of basic pharmaceutical assistance was a result of municipal and state health secretaries' demands for change. The process was precipitated by the various difficulties faced by the Ministry of Health in managing centrally a nationwide programme of basic medicine provision.

According to the respondents, the rationale underpinning decentralisation relied on the potential of local government to improve the access to medicines. Municipal and state health secretaries expected that a re-distribution of power (and resources) to buy medicines according to local needs could solve the provision shortages, and the lack of suitability of the medicines distributed by the federal government.

The process of decentralisation was portrayed as a consequence of primary care decentralisation. After the health reform introduced in 1988, municipalities were in charge of health care delivery and they expected that the management of the provision of basic medicines should be decentralised to complete their autonomy. My interviewees suggested that decentralisation was a gradual and negotiated process that involved the three government tiers, and was coordinated by the Ministry of Health.

The NMP, which provided the legal framework for decentralisation, is seen by the interviewees as an important turning point that allowed medicines to reach a higher position on SUS agenda. The NMP provided a comprehensive policy which included activities beyond the distribution of medicines, and was designed to improve SUS pharmaceutical assistance.

As my interviewees suggested, regional differences in terms of structure and management capability shaped the implementation of decentralisation. In general, these differences resulted in variations in the level of decentralisation adopted: complete (when the municipality has control over the provision of medicines) or partial (when the state manages the funds and purchases the medicines chosen by municipalities). In one option, developed states that have better infrastructure and management capability took upon themselves the tasks related to the purchase and distribution of medicines. This, in turn, corrected the lack of scale and poor administrative capability of small

municipalities to manage the provision of medicines. On the other hand, some states left municipalities with the responsibility for the whole cycle involved in the provision of drugs. Decentralisation in this case has caused serious difficulties, especially to small municipalities in less developed regions. These different panoramas raise questions about the lowest suitable degree to which a specific policy should be decentralised.

After this discussion on how decentralisation developed, the next chapter analyses the particularities and the development that occurred in federative relationships as a result of the health reforms that affected the pharmaceutical assistance field.

## CHAPTER FIVE

### FEDERATIVE RELATIONSHIPS AND BASIC PHARMACEUTICAL ASSISTANCE IN BRAZIL

#### 5.1 Introduction

As discussed in Chapter Four, the decentralisation of the provision of basic medicines was a negotiated process between the three levels of government. Hence, federative relationships and forums of agreement provided in the legal framework were involved in this process. To discuss the influence of these relationships on the provision of medicines, first it is necessary to consider, in a broad sense, how federalism and decentralisation have developed in Brazil, and how power was divided between the central and non-central government.

Brazil has a consensus democracy model.<sup>77</sup> This “model is characterised by inclusiveness, bargain, and compromise; for this reason consensus democracy could also be termed *negotiation democracy*” (Lijphart, 2012:3). This model promotes broad participation and policies implemented should reflect the agreement achieved.

Moreover, Brazil has been governed by a federal constitution since 1890. Miranda (2003:213) remarks that unlike the United States, in Brazil the federation did not arise from independent entities but emerged from the national unity existing at the time of the proclamation of the republic in 1889. While federalism in the United States, for example, originated from aggregation, in Brazil, it is rooted in segregation: the unitary state was divided into several member states.<sup>78</sup> As a consequence, the power of the Union – through public investment, budget allocations and large national projects – became the main element in the construction and consolidation of the

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<sup>77</sup> Lijphart (2012:4) identifies ten variables which determine whether a country is either a “consensus democracy”, a “majoritarian democracy”, or somewhere in between. The institutional design of a fully consensual democracy would allow executive power-sharing to take place through the application of proportional representation to the executive office/branch; it would be a presidential rather than a parliamentary system; the legislature would be bicameral rather than unicameral; the system would allow for multiparty governance; there would be proportional representation in the legislature; interest group corporatism; a federal intergovernmental arrangement with relatively autonomous regions at the more local levels; constitutionally enshrined checks and balances; a judicial review process; and centralised bank independence.

<sup>78</sup> Federation by segregation, or centrifugal, originates from a unitary state, which splits. There is thus the segregation (division) of the central power with the new units. However, larger portion of this power remains with the central government, which restricts the autonomy of member states. In contrast, in federation by aggregation (created as a result of centripetal forces), the state originates from the union of sovereign entities, who renounce a portion of sovereignty to the formation of the federation. It is the example of the United States federation, which resulted from the union of thirteen colonies.

federation. The author argues that the predominant participation of the Union led to an unequal correlation of power between union and other federal entities preventing the federation from acting as a tool for equitable distribution of resources. The persistence of those distortions may be linked to regional inequalities that continue to this day. Although since 1890 the country has gone through important political changes, the characteristic of centralised power in the Union remained.<sup>79</sup> In agreement with this analysis, the Brazilian political scientist Marta Arretche (2012) argues that the process of building the Brazilian federation reinforced the centralisation of political authority.

Federalism tends to be adopted by large countries or societies that have heterogeneity in the territorial, ethnic, linguistic, socioeconomic, cultural or political fields (Lijphart, 2012:183). Two of these characteristics could be assigned to Brazil without dispute: the size of the country and socioeconomic heterogeneity. The purpose of the federation is to maintain social stability in the presence of these heterogeneities. An essential aspect of the federation is linked to its capacity for promoting partnerships among federal entities in order to address conflicts. In this sense, federalism is intrinsically linked to covenants, as pointed out by Elazar (1987:5):

*The term federal is derived from the Latin 'foedus' which, like the Hebrew term 'brit', means covenant. In essence, a federal arrangement is one of partnership, established and regulated by a covenant, whose internal relationships reflect the special kind of sharing which must prevail among the partners, namely one that both recognizes the integrity of each partner and seeks to foster a special kind of unity among them.*

In the Brazilian case, despite the heterogeneity mentioned, several aspects such as language are shared between the federative constituents contributing to maintain the unity. The balance of power however, is skewed to the centre, as this chapter will discuss.

As is well known, in federalism, power and competencies are shared between central and subnational levels, and all intermediate tiers of government have their competencies constitutionally guaranteed. Thus, this system of government imposes a certain level of constraint on central government initiatives. In that way, the federal level cannot invade the competencies of the subnational levels. As mentioned, in Brazil, the legal framework of these relations was set by the Federal Constitution of 1988, which established the federal system as an immutable clause, and also significant to this discussion, introduced the figure of municipalities as autonomous entities.

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<sup>79</sup> In 1890 came the proclamation of the republic which ended the Brazilian imperial period. Since 1891 Brazil had had four other constitutions before the 1988 Constitution, which is currently in force.

The arrangement adopted with three autonomous political entities – the union, states and municipalities<sup>80</sup> – has had, as immediate consequence, the need for redistribution of competencies for the provision of public services between the three spheres of the federation (Guerreiro and Branco, 2011). Indeed, understanding the dynamics of these federal relations is a necessary path to the understanding of the decentralisation process in Brazil. Given its impact on the division of responsibilities and resources between levels of government, these negotiations play an important role in the functioning of government programmes.

With regard to my thesis, pharmaceutical assistance is directly affected by federative relations. In this chapter I will focus on how aspects of the federative pact influence the health system, particularly the management of basic pharmaceutical assistance. This chapter is organised in six sections. Following this introduction, the second section analyses the reforms in the 1990's and how these affected the health system. The third section introduces the roles and responsibilities of the federative units regarding the health system, and their implications for coordination and autonomy. The fourth section explores the federative relationships concerning the management of the health system, especially basic pharmaceutical assistance. Closing the chapter is a discussion of how disruption of pacts and the lack of accountability affect the provision of medicines, followed by the conclusions.

## **5.2 Cardoso's reforms and the emergence of fiscal and health decentralisation**

To understand current governmental relations concerning pharmaceutical assistance policies we need to go back in time to significant events regarding fiscal and health decentralisation that impacted the way the pharmaceutical field is managed. Fiscal conflicts between federal and state level are a persistent issue in Brazil and were particularly important in the 1990's (Samuels 2004:120). In order to reduce the fiscal and economic crisis in the mid 1990's President Cardoso (1995-2002) went through efforts to restructure Brazil's intergovernmental fiscal system, reducing the state's fiscal autonomy. President Cardoso was elected in 1995 on the back of the 'Real Plan', a package of economic measures that helped to stabilise the economy and control inflation, and which introduced the Real, the new currency. This economic plan was implemented when Cardoso was the Minister of Finance, in 1994. Dickovick (2003:6) argues that the success of the Real Plan

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<sup>80</sup> The three levels of government - federal, state and municipal - have elections for the executive and legislative branches; have substantial administrative autonomy; have authority to legislate in different public activities, as well as capacity for tax collection and expenditure of their own. In Brazil, municipalities are federal entities and have administrative, political and financial autonomy, being empowered to collect, monitor and expend revenue from resources.

allowed Cardoso to change subnational autonomy by tightening ministerial control over expenditure. Dickovick (2003:9) shows the correlation between the reforms of the 1990's and political proximity to President Cardoso. The author argues that close ties between the President and Ministers led to important fiscal and administrative changes, notably in education and health. In Ministries controlled by the president's political party new expenditure rules were developed. These rules linked the transfer of funds to an increase in provision of services, mostly at the local level, so that the state level was being bypassed.

Reforms in health, with the establishment of the National Health System-SUS, created links with municipalities and transferred funds and responsibilities directly to municipalities. These transfers of funds increased in accordance with the level of services provided by municipalities. This central-local linkage helped municipal government to develop health provision capacity and allowed federal government to bypass the state level for substantial portions of the health budget. Dickovick (2007:15) argues that this empowerment of municipalities in Cardoso's government contributed to restraining the state level power<sup>81</sup>. The 1988 Constitution reduced the possibility of major fiscal centralisation by the federal level, so the Cardoso government used expenditure municipalisation to control public spending at subnational levels and curb the strengthening of the state level within the federation. The direct fund-to-fund transfer from federal to municipal level decreased the power of the state, but it also removed the municipality's discretion over health spending because the funds transferred were earmarked. This weakening in state level leverage, along with the direct linkage between central and local levels will be important to explain other developments in the provision of basic medicines. Within those changes, the next section will discuss how the new roles and responsibilities were echoed in the pharmaceutical assistance field.

### **5.3 Roles and responsibilities: coordination, interdependence and autonomy**

The competencies, roles and responsibilities of each level of government in SUS were defined by the 1988 Constitution and the 8080/1990 Organic Health Act. However, it took several years for the roles and responsibilities of each of the three levels to be made completely clear and put into practice. Coordination and interdependence have complex boundaries in Brazil because few exclusive competencies exist at any level. Health financing responsibilities are shared between all

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<sup>81</sup> Other factors that contributed to undercut states were the new fiscal responsibility law, which limited the spending of states and municipalities to the taxes collected, and the privatisation of state-owned banks.

three government levels. Municipalities are responsible for health care delivery and are autonomous entities, so federal and state level do not have jurisdiction over them.

The three levels of government, with shared competencies and power, which resulted from the 1988 Constitution, required the deployment of institutional mechanisms for intergovernmental articulation. These mechanisms were necessary to connect obligations with resources. This meant that the distribution of responsibilities and powers that resulted from decentralisation introduced the need for negotiation previous to the implementation of policy and health programmes. Subnational autonomy meant that those actors had to be persuaded and encouraged, and more importantly, had to agree to follow the guidelines issued by the Ministry of Health.

Although state and municipal levels participate in important ways in the development of many aspects of health policy guidelines (operation, management, financing) through different intergovernmental forums (such as CIT, CIB, CONASS, CONSEMS, CNS, and Health Conferences about which I will give more details later in this section), individual states and municipalities have no political authority over the basic parameters of health policy within their jurisdictions. The setting of these parameters is a federative matter (Chapman Osterkatz, 2011). This includes the minimum health care activities that must be delivered, such as a pre-set number of antenatal consultations or compliance with a compulsory vaccination scheme. Individual states or municipalities also have no political authority to restrict the private health service within their jurisdiction. Despite this, sub-national governments may choose how they will fulfil their obligations established under national law. While sub-national units have to comply with spending requirements for health, they are not constitutionally bound to follow the programmes developed by the Ministry of Health. In order to avoid non-engagement, since the mid-nineties the central government has largely used incentives and conditionality to encourage subnational cooperation (Dourado and Elias, 2011). The development of such mechanisms went a long way to support the implementation of decentralisation. At the start, Ministry of Health ordinances and earmarked funds encouraged the adoption of decentralised initiatives by subnational actors. These mechanisms were eventually substituted by intergovernmental pacts.

The process of negotiation is designed to conclude in an intergovernmental pact, which translates into a signed contract with all the clauses negotiated between the governmental agents. These instruments of agreement were an innovative feature introduced in health management after the enactment of the 1988 Constitution (Guerreiro and Branco, 2011). The method encompasses continuous negotiation in order to reach an agreement regarding intergovernmental conflicts, which

is particularly relevant within federative arrangements, where each governmental level has autonomy. Guerreiro and Branco (2011) argue that the approach to the agreement that emerged in the framework of public health management has its origins linked to the restructuring process of Brazilian public administration. These reforms, in tune with the neoliberal winds at that time, preached a reduction in the size of the State and a reorientation of its functions. The federal level, in the course of these reforms, started to be in charge of coordination, stimulation and financing instead of performing public policies, i.e. the subnational level became responsible for the delivery of public services. Thus, decentralisation required the strengthening of coordination mechanisms since it interfered with the existent balance between autonomy and interdependence of governments (Abrucio, 2005). This balance was particularly affected in the case of pharmaceutical assistance, as I will discuss.

Among the aspects that facilitated the adoption of intergovernmental pacts in the health sector, political and administrative decentralisation and the forums of agreement and decision provided within the structure of the SUS stand out (Guerreiro and Branco, 2011).<sup>82</sup> The forums of federative articulation in the SUS included in the federal legislation are: the National Health Council (CNS); Bipartite Intergovernmental Commission (CIB); Tripartite Intergovernmental Commission (CIT); National Council of Municipal Health Secretaries (CONASEMS); National Council of State Health Secretaries (CONASS) and the Council of Municipal Health Secretaries (COSEMS).<sup>83</sup> Nonetheless, some of the features of SUS that prompted the adoption of the strategy of pacts are also identified as factors that hindered their implementation. The main difficulties and contradictions that have reduced the efficacy of these pacts, as pointed out by D'Avila *et al.* (2002), are: decentralisation itself and the need for co-operation among federal entities; intergovernmental relations marked by conflict and competition for resources; excessive centralisation and institutional fragmentation; fragile regulatory capacity; and negligible social participation. Many of the difficulties pointed out by the author in 2002 are still valid today, as some of the interviewees' accounts explored later on in this chapter will illustrate.

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<sup>82</sup> In Chapter One, Figure 1.1 shows the SUS forums and mechanisms for operation and coordination.

<sup>83</sup> The CIT is a space for articulation, discussion, and agreement of the demands from federal, state and municipal managers, being formed by the three instances of SUS: The Union, represented by the Ministry of Health, states, represented by the National Council of State Health Secretariats (CONASS) and the municipalities represented by the National Council of Municipal Health Secretariats (CONASEMS). The CIB works similarly with representatives of municipal and state level. The main functions of CIT and CIB are related to operational aspects, financial and administrative management of the SUS, as well as network and health services integration among the federative entities.

Dickovick (2007:20), in line with D'Avila *et al.* (2002), argues that decentralisation – of political, fiscal and/or administrative authority – from the central government to local governments can weaken the intermediate levels (the state level in the Brazilian case), thus undermining federalism. The process of health reform decentralised responsibilities and resources to the state level, but mostly to municipalities. It is also true with regard to the decentralisation of basic pharmaceutical assistance.

As discussed in Chapter Two, decentralisation has the potential to adapt policies to local conditions and to increase the participation of the population; but it can also lead to inefficiencies due to loss of scale and scope, fragmentation of services and the difficulty of coordination of actions. As in the health sector in general, an important challenge posed by decentralisation of basic pharmaceutical assistance is the need to enhance effective state coordination of the municipalities.

Although the management of basic pharmaceutical assistance is a local responsibility, municipalities are supposed to have technical assistance and financial support from state and federal levels to perform their duties. Nonetheless, in cases where, for instance, the state level does not fulfil its responsibility, neither the municipality nor the federal government have jurisdictional control to enforce compliance. Regarding basic pharmaceutical assistance, some of the problems produced by this autonomy are exposed by the interviewees, as is illustrated in the two quotations that follow. The interviewee associated the weak performance of the state in fulfilling its responsibilities with the judicialisation issues:<sup>84</sup>

*So, in states such as São Paulo, which has an important judicialisation demand, the state got involved [with judicialisation issues] and stopped supporting the municipalities in the structuring, planning, and technical support for basic pharmaceutical assistance. But it is happening in many states. (Interviewee 19, 12.1)*

*(...) the municipalities, especially small and medium-sized ones, need too much technical and financial cooperation from state governments, and the state level in São Paulo has abandoned that approach. Rather, the structure of the state [health] secretariat today was dismantled. So fragmentation is very strong (Interviewee 1; 33.1).*

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<sup>84</sup> Judicialisation is a phenomenon experienced in Brazil, occurring when patients take the government to court for access to health services and resources (in this particular case the term refers to lawsuits for access to medicines). See Chapter Four for more details.

These two quotes also suggest that the state level is committed to other activities linked to judicialisation and this has left municipalities vulnerable. São Paulo is an influential state situated in the most developed region of Brazil, and for this reason it would be expected to have the best conditions for delivering public services. So if the municipalities have a struggle in terms of coordination and technical cooperation to manage the provision of medicines even in São Paulo, then it is plausible to think that the small municipalities in less developed areas around the country will have the same difficulties.

When I compared, within the accounts I gathered, the views and perspectives of state and municipal health secretariats it becomes apparent that the state level has other priorities in terms of pharmaceutical assistance than to assist municipalities with the provision of medicines. Decentralisation of the provision of basic medicines to municipalities certainly plays an important role in explaining this change in priorities. The state level, however, still has responsibilities and its role in co-funding, technical assistance and cooperation is not disputed, as voiced in the following quotation:

*When we decentralised and brought to the municipalities the responsibility for basic pharmacy, with the exception of those states that have centralised purchasing [partial decentralisation], a lot of the role of the state was lost. It has neglected much of its role of supporting municipalities. (...) In 2009 TCU made a big audit in ten states and three municipalities on basic pharmacy.<sup>85</sup> The report points out that the state has lost its role of providing technical support for municipalities. The report says that state and Union are not doing anything in relation to pharmaceutical assistance policy. I think it's an overstatement. But the state neglected its supporting role and it is more in control of resource transfers, and forgets its role in helping the municipality in planning and structuring. (...) So I believe that in some states this process went too far away. Municipalities were [left] alone in the basic pharmaceutical assistance. The state got more involved with specialised components, high-cost drugs, and judicialisation (Interviewee 19; 12.1).*

The interviewee brought to light an important report conducted by TCU in 2009 that resulted from an audit related to basic pharmaceutical assistance (TCU, 2011). The report showed important failures in the coordination and cooperation among federal entities. According to the audit that analysed ten states, the Ministry of Health should provide technical cooperation to states and

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<sup>85</sup> TCU is the Court of Accounts of the Union

municipalities, to standardise patient care and quality of the service. However, according to the report, the federal level does not guide or advise municipalities in the process of acquisition and dispensing of medicines, just as it does not provide incentives or induce states to provide technical and financial cooperation for municipalities in activities related to basic pharmaceutical assistance. The TCU report also pointed out that the state governments do not perform their duties defined in the National Medicines Policy (NMP). The audit team argues that states neglected their role in assistance, coordination, provision of technical support in the process of acquisition of medicines, and did not support the organisation of consortiums. The state level, with respect to pharmaceutical assistance, is focused on providing high-cost medicines that are part of a particular category of drugs, termed the *specialised component*.<sup>86</sup> TCU's report was emphatic in stating that neither the federal nor state level has fulfilled their role. My interviewees, nonetheless, suggested that the main concern of municipalities was focused on failures at the state level. The explanation for this perspective could be associated with co-funding issues. As discussed, co-financing is an essential part of the health system, and failures at any government level in sending funds can cause interruption in the provision of medicines in municipalities. Interviewees reported many situations where the state level did not perform as expected in co-financing, but are categorical in stating that the federal level never fails to transfer funds.

Although all interviewees mentioned the importance of the autonomy of federated entities and institutionalised forums of agreement within the SUS structure, there is an understanding at the Ministry of Health that this process of persuasion and agreement with the federated entities is very time-consuming. Autonomy is also seen as a barrier to the implementation of policies. The delay in negotiations with sub-national partners is contrasted with the speed observed in the private sector. Talking about the implementation of the Popular Pharmacy Programme (which is the subject of Chapter Seven) and the need to implement a database system to record information about patients treated at private pharmacies, the interviewee compared response times of public and private sectors:

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<sup>86</sup> The *specialized component* of the pharmaceutical assistance is related to medicines that are part of the Clinical Protocols and Therapeutic Guidelines. They are organised in four groups. The state health Secretariats are involved in the following steps of the management:

*Group 1A:* storage, distribution, and dispensing.

*Group 1B:* purchase, storage, distribution, and dispensing.

*Group 2:* co-funding, purchase, storage, distribution, and dispensing.

*Group 3:* co-funding.

*In the 30 days since President Dilma decided that hypertension and diabetes medicines would be distributed free of charge across the community [pharmacies] network, the pharmaceutical market has managed to get organised in 30 days to change the computer system [software], to adapt the prices, and to organise all the logistics. Yes, they have done all that in 30 days. For two and a half years I've been trying to [develop] a system to make that information on access to SUS public pharmacies network available (...) I've said this before, in 30 days the whole of Brazil was mobilised. On the other hand, we took two and a half years to get 170 health units, and are still begging for health secretariats to use the system [HORUS] <sup>87</sup>... So it's very different [from the private sector]. Public [sector] feedback is very time-consuming (Interviewee 19; 11.2).*

The situation described by this interviewee suggested that failures and delays inherent in the negotiation process among the federal, state and municipal levels seem to lead the federal government to seek alternatives in order to shorten this process of negotiation. The autonomy of municipalities to follow federal programmes is also associated with delays and difficulties in implementing federal initiatives (in this case the interviewee refers to the database system that monitors pharmaceutical assistance, known as HORUS, proposed by the Ministry of Health). In the previous quotation, the Ministry of Health official emphasised the difficulties in engaging health secretariats, using the word 'begging'. In contrast to this time-consuming negotiation with the public sector, the private sector was portrayed as responding swiftly to the federal level demands and, more importantly, without needing a negotiation or agreement process. The introduction of a new actor, the private sector partner, in the implementation of a particular policy illustrates how federative relationships in pharmaceutical assistance are currently being reshaped.

#### **5.4 Development of federative relationships in pharmaceutical assistance**

Despite the difficulties and delays intrinsic to negotiation processes, my interviewees considered federative relations to have improved with the changes implemented via health pacts and the inclusion of the forums of agreement in the policy process.

SUS has been experiencing a continuous change in central-local relations over the last 20 years. In the 1990s and early 2000s the strategy adopted by the Ministry of Health with the implementation

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<sup>87</sup> HORUS is software to manage pharmaceutical assistance implemented by the Ministry of Health; it allows the control and distribution of medicines by SUS.

of SUS, by publishing legal standards, was summarized in the familiar expression "carving out the SUS by decrees" coined by Goulart (2001).<sup>88</sup> Pasche *et al.* (2006) argue that although some of the Ministerial regulations, such as the NOBs<sup>89</sup>, had been agreed in intergovernmental forums, the term 'regulatory frenzy' came to be used to describe the process of bureaucratisation implemented by the federal executive. In the late 1990s, the Ministry of Health published, on average, eight orders per day. Pasche *et al.* (2006) state that the normative approach adopted was drawn from the analysis that the main problem in SUS was low management capacity in the subnational tiers. Thus, the regulations were intended to limit the degree of control that local managers had over the federal resources allocated.

As the decentralisation of health has progressed and states and municipalities have taken on more responsibilities and developed administrative capacity, the allocation of federal funds has also followed this trend. The rules that guided the transfer of federal funds to finance health services underwent gradual adjustment, changing from payment after service delivery to payment in advance based on agreed goals. The institutionalisation of results-based planning introduced by the Portaria 21/2005 (Ministerio da Saude, 2005a) and the *Pacto pela Saúde*<sup>90</sup> (Ministerio da Saude, 2006) and, most recently, by Decree 7508/2011 (Brasil, 2011), which strengthened the mechanisms of accountability, are important inflection points within the course of SUS development. In general, those policy changes towards agreements other than rigid normative rules (such as the NOBs) are acknowledged by the interviewees as positive and promising initiatives. Those changes are seen as an advance in central-local relations, as explained by this interviewee:

*SUS is undergoing a transition. There was a time when SUS was formatted by very rigid orders and regulations, but now this has evolved to a different paradigm regarding the relationship of accountability and also federal funding. Now, there is a commitment to goals that, together, the three entities [federal, states and municipalities] believe that it will be possible to achieve. These goals are to promote the health of the population. The prime example of this is when today the Ministry speaks of advanced global financing. So, what*

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<sup>88</sup> Although Goulart (2001) used the word 'decree', in fact the Ministry of Health uses ministerial orders. Thus, the more precise wording would be: 'carving-out the SUS by ministerial orders'. I think the author chose the term 'decree' because in Brazil, in colloquial language, is common to use this word to refer to something that is seen to have been imposed.

<sup>89</sup> NOB - The organization and operation of SUS were guided by rules known as NOBs (Basic Operating Standards), developed throughout the 1990s and 2000 to regulate the system operation. However, the use of these standards has created dependency on the system of issuing ministerial orders. The NOBs favoured the transfer of earmarked financial resources and created a system of prior qualification of municipalities to receive federal funds, which increased health inequalities in the country.

<sup>90</sup> *Pacto pela Saúde* means 'Pact for Health'.

*once was paid only a posteriori, after undertaking the health procedures, now is to be paid in advance, on a global basis in accordance with the agreed targets. We'll have to try it. It's a different way of forming a relationship. We walk towards it, to move further forward (Interviewee 5; 12.1).*

From this quotation we can see the association of particular funding rules (payment after service delivery versus payment in advance) with the development of central-local relations. The negotiations to set goals and the payment in advance are taken as a signal of a change in these relations. Another valued characteristic refers to the institutionalised mechanisms to allocate resources that prevent political alliances from prevailing in the division of resources. The architecture of the forums of negotiation (COSEMS, CONASS, CIB and CIT) provides mechanisms which allow transparency in the allocation process.

Funds allocation follows the same established rules applicable to each federal entity. However, if there are additional funds to be reallocated that escape this general rule the division follows another agreement route. As the allocation and use of funds have to be justified and negotiated, the scrutiny of peers precedes the effective allocation of resources. This municipal health secretary from São Paulo state summarised this mechanism in the following quotation:

*I would say that SUS today - this is very interesting - that despite all the political and partisan character, despite all the difficulties, [despite] the cronyism that is characteristic of Brazilian politics, despite all, that SUS has a republican character. In resources allocation, for example, we have R\$40 million for elective surgery sent by the federal government to spend until the end of this year. Instead of deciding: I'll send it to São Bernardo because they are PT [the Workers Party, the party of the president of the republic], or to such-and-such a place which is PMDB [this party is included in the government coalition] because I have to please the mayor, what does the government do? The money is allocated to the state and then seven municipal secretariats and seven state secretariats in the bipartite commission [CIB] will decide. We [municipal secretaries] represent 645 municipalities and they [the state managers] represent themselves. We have the responsibility for deciding and agreeing on how this resource will be spent. To make this allocation I had a board meeting yesterday with two, and today with 64 members who are regional representatives of 64 regional management boards. In this game, there were more than 80 municipal secretariats involved in deciding how we will spend R\$40 million. If a municipality is privileged the other municipalities will disagree and denounce it (Interviewee 1; 29.1).*

Thus, as clearly shown in the quotation, forums of negotiation play an important role in ensuring transparency in the distribution of federal funds within each state of the federation. The inclusion of representatives of municipalities neutralises possible partisan political influences on the process of reallocation of resources. Although the interviewee referred to health services, the same reasoning and forums of agreement are applicable to pharmaceutical assistance. However, these forums are not sufficient to ensure the state level's accountability regarding pharmaceutical assistance, as will be discussed in the next section.

### **5.5. How ideology and party politics may influence the continuity of health initiatives**

Although the role of ideology in the implementation of health policies in Brazil may be disputed, my interviewees considered that ideological divergences and party-political affiliations can have a negative impact. According to their accounts, the willingness of politicians, at the state level, to make it clear to their constituency that they run counter to the federal government usually results in a failed attempt by the Ministry of Health to implement certain national initiatives. According to one interviewee, the divergence between the government of São Paulo state and the federal government, which are from different political parties, pushed the state secretariat to lead the health policy in the opposite direction to the orientation of the federal government. This claim is well illustrated by the following quotation:

*If the state government was more cooperative, and fought less with the federal government, as is happening now in this second administration of the state government; if they had at least a little better alignment... Because here in São Paulo it was always like this: if the federal government wants this, then the state does not do that (Interviewee 1; 32.1).*

One example of this confrontational approach can be observed in the implementation of the Family Health Programme (PSF). In São Paulo the PSF was handed over to the OSS<sup>91</sup> (Social Health Organizations), making the features of the programme distinct from the PSF in other regions of the country (Chapman Osterkatz, 2011). Although the guidelines and directives are set by the federal government, there are considerable variations in local government's willingness to follow them and to adopt the policy proposed. The motivation to implement national programmes may be related to

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<sup>91</sup> The Social Health Organization (OSS) represents a partnership model adopted by the government of the State of São Paulo for the management of health facilities. State law regulates the partnership with charities, which have become categorized as Health and Social Organizations, being able to sign a Management Contract with the State Health Secretary, directed towards the management of hospitals and public health facilities within state territorial jurisdiction.

political partisanship. Sugiyama (2007:8) investigated the motivation for the diffusion of innovations in the health field across Brazil, using the PSF as a case study, and argued that “ideology and social networks can work together in mutually reinforcing ways to promote diffusion.”

State health secretariats’ control over the implementation of decentralised initiatives for supply of medicines and sharing of power with the municipal level are other aspects mentioned by the interviewees. The next quotation illustrates how personal perspectives can influence the decentralisation process:

*So the municipalities had an important role in the decentralisation process. But the state manager ends up being a hostage of political forces to decentralise or centralise, to empower municipalities or not. Finally, depending on the current political forces, they can divide responsibilities and effectively implement the decentralisation or they can adopt another form to deal with the federative relationship (Interviewee 4; 5, 4).*

The view expressed above is in accordance with Sugiyama’s (2007:8) affirmation that ideology helps individuals to filter their policy choices. The interviewee associated the decision to implement decentralisation to state level political ties. This became apparent when the interviewee said that depending on the political forces the state could follow federal policy and effectively decentralise responsibilities to municipalities or not. The two previous quotations suggest that at the state level the political group plays an important role in explaining differences in the level of decentralisation<sup>92</sup> implemented and the adherence to federal policies. In São Paulo, basic pharmaceutical assistance was partially decentralised, i.e. the state controls the provision of basic medicines, and only a few municipalities within the state have complete control over basic pharmaceutical assistance. Looking at partisan differences over the last ten years (2003-2013), since the first Workers’ Party presidential government, São Paulo state has been ruled by the opposition party to the federal government, which could explain the interviewee’s analysis of the dichotomy between federal and state government when it comes to health initiatives.

In contrast, states where politically appointed officials are less frequent and influential do not experience this strong political influence of state level authority. The accounts of my interviewees suggested that less political interference will result in less political appointment of officials. This in

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<sup>92</sup> In Chapter Four I refer to partial or complete decentralisation to differentiate what I termed “levels of decentralisation”. Partial refers to decentralisation from central to intermediate level, in this case state level; and complete when power and responsibilities are distributed to municipalities.

turn will give opportunity for continuity. If the officials are career civil servants they are more likely to remain in office for longer, in contrast to the high turnover of political appointees. In the next quotation, this state health secretary associates less political interference in policy implementation with better health outcomes:

*I think an important point in the state was continuity in policies for health. We had a continuity of people who are extremely committed, secretaries extremely committed to public health, regardless of ideology or party affiliation. We actually experienced this continuity and that advance is demonstrated by our health indicators: the reduction in infant mortality... (Interviewee 2; 15.1).*

Turnover in most ministries in Brazil, including the Ministry of Health, is quite high (Sugiyama, 2007:102). Usually, after general elections ministerial change is accompanied by a cascade of changes in state and municipal health secretaries, who are also appointed rather than being career civil servants. The political appointments are not limited to the upper levels of management. This lack of continuity in professional teams affects the implementation of health policies, making the process slower, less cohesive and more difficult. The potential incremental gain that results from experience acquired after some time working in a programme is broadly offset by turnover. Each new health minister or secretary wants to make their own mark on management and employ people who share their goals and values. If on the one hand it is hard to prove or to provide evidence that lack of continuity negatively influences policy implementation and outcomes, on the other hand examples of states that have experienced fewer changes in their officials offer good examples of what could be achieved.

The medicines consortium implemented by Paraná state, which is always cited as a successful initiative, is associated by the interviewees with a committed professional group of career officials.<sup>93</sup> The fact that the initiative to create the consortium came from an established professional team, which currently still works at the state health secretariat, was pointed out as a crucial factor to explain the success achieved, as claimed by this interviewee:

*It [the consortium] was a pioneer initiative of Paraná. It was the result of the autonomy and the result of efforts made by the State Health Secretary who, at that time, believed in the success of this initiative. Especially because many leaders who worked in the team*

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<sup>93</sup> The innovation introduced by the Paraná consortium and details about its management is discussed in Chapter Four, section 4.5.

*remained or returned, believing that consortiums were a better solution and more effective for the problems that were common to municipal managers (Interviewee 3; 2. 1).*

Discussing the circumstances in which this consortium initiative took place, two factors emerged from the interviews: professionalism and continuity. These factors help to understand the special features found in Paraná state which allowed the emergence of the consortium. Professionalism refers to the team's training being focused on the area of health and also refers to the career officials or civil servants. It may seem incongruous that people occupying important positions do not have specialised training. But it occurs with some frequency in Brazil when it comes to politically appointed positions.

The importance of professionalism and the continuity of the working group, despite party-political changes, were identified as factors that differentiate Paraná state, and were also associated with positive results achieved. This view is not only an inside observation but it is shared by Ministry of Health officials, as illustrated in this quotation:

*In Paraná it is different, pharmaceutical assistance works. First you have a team in the state that is very different from other states, a team of pharmacists who managed to maintain the continuity of the work in the state, regardless of changes of government (interviewee 19; 12.2).*

The political and partisan influence in the nomination of teams and leaders in health are part of the political culture of the country. Yet considering the potentially negative effect of this practice on policy implementation, to counteract this tradition is not a straightforward task. Even if the Ministry of Health wanted to act, it would not be feasible to set out ministerial orders to change the behaviour of subnational actors prohibiting this practice. A ministerial order, of course, does not have the same legal power as parliament norms. Even if it had, however, it could not be used for this purpose because this would constitute interference in the autonomy of states and municipalities. Moreover, the appointment of ministers and officers in the upper levels of management also follows party affiliation, so it would be incoherent to ban this practice just in the states and municipalities.

Thus, as this section has highlighted, political autonomy combined with the power distributed by decentralisation led to the achievement of positive results, such as the consortium in Paraná. Moreover, this same arrangement also enabled federative entities to continue working under strong

partisan influences. The accounts of my interviewees suggested that the high turnover experienced in some parts of the country prevented the continuity of staff and might have caused programmes to be discontinued or not to progress. This situation resulted in teams not being committed to national programmes and could explain the failure, especially at state level, in fulfilling agreed tasks. This lack of commitment to the pacts signed is going to be explored in the next section.

## **5.6 Disruption of pacts: failures and lack of accountability**

Like other health-related fields, inequalities are still an important issue in public provision of medicines. Moreover, the differences in terms of coverage level and access between regions are remarkable. As discussed, the budget for basic medicines is co-funded by the three government tiers, and although the role and responsibility of each level is explicitly stated in legislation, interviewees reported a systematic inconsistency in state level financial support. One might expect this failure to occur in less developed regions or states, but accounts of this type came from a municipal health secretary from São Paulo state, which is one of the wealthiest states of the federation. Certainly, the failure in contributing to financing has negative consequences for municipal planning and for provision of medicines. These failures at the state level in fulfilling its responsibilities and the consequences that follow are illustrated by this interviewee from São Paulo:

*I would say that the great difficulty that we have here, in São Paulo state, is the fact that the state government does not fulfil its part in the pact, and it is important to say that the Ministry [of Health] does not fail. The money is little, but it comes religiously! Now the state government is not doing its share in basic pharmaceutical assistance ..., either delivering the drugs or the funding ... (Interviewee 1; 38.1).*

In São Paulo, as discussed, pharmaceutical assistance was decentralised just down to the state level. Municipalities opted to leave the state level with the responsibility for the management of resources and procurement of basic medicines. The interviewee remarked that the federal level is sending its funding share to the state but the state keeps the money and does not distribute the medicines to municipalities.<sup>94</sup> This interviewee explained that these issues are constantly part of the agenda and they represent a significant proportion of the discussions that take place at the CIB in this state.

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<sup>94</sup> This municipal secretary of health showed me a spreadsheet depicting the two-year delay in transfers of funds due by the state level.

My interviewees suggest that the impact of these failures on federative relations is an object of concern at the federal level. According to one Ministry of Health official, the debate in the agreement forums has been much concentrated on negotiations about transfers of resources and the frequent failures of the state level in fulfilling their responsibilities. When talking about the municipal health secretariats' meetings which precede the CIB meetings, this official argued that:

*I visited all COSEMES [forums] in these last two and half years.... Many states and municipalities are discussing whether the state will transfer the funds, if the state is not transferring regularly, if it is behind schedule. That's all they discuss there (Interviewee 19; 12.1)*

Funding is a real issue for municipal managers and consequently it should be part of the negotiation agenda in CIB and CIT. Basically, in these forums the three tiers will negotiate tasks, responsibilities, and discuss whether the funds proposed (usually by the federal level) are sufficient to finance the tasks agreed. The accounts of my interviewees, however, suggested that other themes did not get the chance to be discussed, such as the issue of pharmaceutical assistance *per se*. Discussions about the insufficiency of funds and the lack of accountability of the state level in fulfilling their responsibilities, in contrast, were (and are) recurrent themes dominating the agenda in CIB forums. Of course, without medicines there is no pharmaceutical assistance, and the debate about issues of lack of sufficient funding or resources is essential. My interviewees suggested, however, that the inconsistency in transferring funds is preventing other subjects from entering the agenda and consequently preventing the potential evolution of public policies and of the decision-making process at the local level.

Although annual overall expenditure on health represents 8.4% of GDP in Brazil and is close to the world average of 8.5%, according to the WHO, the chronic underfunding situation of SUS is well known (Ocké-Reis and Marmor, 2010; Santos, 2007). Moreover, in Brazil, only 45% of health expenditure is in the public sector, with the other 55% being spent on private care. The share of public spending on health is 3.7% of GDP while the international average is 5.5%. Public health spending in Brazil is much lower compared to countries that have universal health systems. These countries spend on average 6 to 7% of GDP (Ocké-Reis and Marmor, 2010). The discussion about public health system financing is a constant item on the agenda of national political debates. States and municipalities are constitutionally bound to spend 12% and 15% of gross revenue on health, respectively. The federal government, on the contrary, has no specific percentage to fulfil. However, in terms of basic pharmaceutical assistance, complaints and faults mentioned by interviewees more often than not refer to the state level. According to my interviewees,

municipalities, which by constitutional duty should contribute proportionally with more resources to health, also have to pay the states' share when these agents fail.

Data from my interviews also indicated that these issues between state and municipalities could lead to an unexpected outcome. This failure of the state level in fulfilling their responsibilities on the provision of medicines or on their share of the co-funding provided a fruitful opportunity for the municipal level to exercise power and to influence the development of a solution. One interesting example came from Bahia, where the state level had a debt with the municipalities related to co-funding of pharmaceutical assistance. According to my interviewees, in 2007, after years of complaints headed by municipal secretariats represented by the COSEMS, the health state secretary proposed an additional programme to distribute diabetes and hypertension medicines to municipalities to be implemented with state funding and planning. The *MEDCASA* programme was designed to enhance the provision of medicines in municipalities as a compensation for years of state lack of compliance with its share in the co-funding of pharmaceutical assistance.<sup>95</sup> The way the process occurred and the main actors who participated in the construction of this alternative are described in the next quote, according to the viewpoint of a municipal health secretary in Bahia:

*The process began in 2007, improving the regularisation of the distribution of drugs by the state. Before 2007 there was a debt of more than R\$ 30 million of transfers from the state to the municipalities [with regard to] Pharmaceutical Assistance. In this context the state proposal to create the MEDCASA programme came up as a way to pay the debt. This was a way to decentralise and to regularise the counterpart. I'm giving credit to COSEMS, which fought for these transfers and to SESAB [the Bahia Health State Secretariat ] for understanding that it was its duty to recognise the liability of counterparts due (Interviewee 10; 3.1).*

In the *MEDCASA* programme, the above account suggests that autonomy and interdependence of federative entities, and SUS forms of institutionalised agreement, came together to develop a negotiated solution which resulted in better access to basic medicines for people living in the region. This example suggests that forms of negotiation can effectively be used to neutralise or reverse negative situations, and I would say in a certain way to enforce liability.

Despite the broader claim, in the literature, that the performance of the decentralised provision of medicines is mainly affected by a lack of definition of roles and responsibilities of the subnational

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<sup>95</sup> The *MEDCASA* programme is discussed in Chapter Four.

actors involved, in my interviewees accounts the lack of accountability was a major issue, as expressed in the following quote:

*I think the fulfilment of these responsibilities, rather than the definition, although in some cases the definition of responsibilities could be renegotiated, but those agreed should have been completed ... Moreover it is a problem which is not unique to pharmaceutical assistance, it exists in all areas: the low level of accountability and lack of consequences which arise from not fulfilling what was agreed. Everyone signed a management pact in 2006 and pharmaceutical assistance was one of the items. This pact was renewed in 2009 and updated in 2010. ... Whoever acts in accordance with the pact is OK, but what happens to those who do not comply? Nothing happens (Interviewee 1; 34.2).*

This interviewee linked the lack of mechanisms to enforce federative entities to comply with the pacts with the perpetuation of practices that weaken the performance of municipalities. In the ministerial rules the only penalty provided for cases of mismanagement is the suspension of transfer of funds, which can occur due to the non-application of municipal or state counterparts or because of irregularities pointed out by audit and control institutions.<sup>96</sup> But, although control bodies had pointed out numerous irregularities in the use of the resources of Basic Pharmaceutical Assistance, as well as the fact that municipalities and states do not make their share in the co-funding available, the transfer of funds by the Ministry of Health was never suspended (TCU, 2011). In the case of no co-funding contribution from the state, TCU (the national auditing tribunal) argues that there is no penalty for the state, which could encourage the omission of responsibilities. According to the audit office's report this fact allows years to pass without some states making the transfer of funds related to pharmaceutical assistance. In my research, this practice was corroborated by interviewees' accounts from São Paulo, Bahia and Amazonas.

Another aspect that arose from my interviews was related to the provision of technical assistance to enable the municipalities to develop better capabilities to perform their responsibilities in planning and delivering basic pharmaceutical assistance. Besides the issue of accountability, the state's role in the coordination and technical cooperation with the municipalities is also the subject of discussion among municipal health secretariats, as exemplified in this quotation:

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<sup>96</sup> The institutions that have direct relation to SUS activities are: TCU - Court of Accounts of the Union (the Brazilian federal accountability office); CGU - The Office of the Comptroller General (the agency of the Federal Government in charge of assisting the President of the Republic in matters related to defending public assets and enhancing management transparency through internal control activities, public audits); and DENASUS - National Department of Audits of SUS (in charge of specialised supervision and audit activities within SUS).

*The central question in Bahia was not only the agreement process itself. The issue was to ensure that what was agreed would be fulfilled, i.e., compliance with the covenants made in the political arena of the CIB [interstate forum]. It was a source of tension between managers, but there was also negotiation and consensus. However, some agreements were not respected, and the state justified the breach of covenants as budgetary or financial difficulties. The state, instead of exercising technical cooperation to support the municipalities in the management of Pharmaceutical Assistance, to help municipalities to strengthen management capacity, and the implementation of pharmaceutical assistance policy, the state did the reverse. So, by failing to empower municipalities it was as if the state had boycotted what had been agreed. (Interviewee 4, 6.1)*

This interviewee expressed disappointment with the state level, because it did not support the development of management capabilities or the financing and distribution of basic medicines, both of which would be the state's role and responsibility. Accountability is still a serious problem, which arguably may have its roots in the creation of SUS. As explained by Chapman Osterkatz (2011), when exploring the historical perspective of health decentralisation, subnational governments gained fiscal and policy autonomy without the presence of accountability mechanisms designed to ensure management capacity, quality of services or access. According to the author, some of the most extreme inequalities in the Brazilian health system are associated with the lack of accountability for subnational governments that do not fulfil their obligations. Concluding this section, I would say that accountability issues combined with the incipient SUS supervision contributed to perpetuate these inequalities.

## **5.7 Conclusions**

This chapter discussed how federative arrangements regarding the health system have affected the decentralisation of the public provision of basic medicines. As discussed, the federative arrangement and the decentralisation process that at the same time allow and presume negotiations and partnerships, also presuppose autonomy, which adds considerable complexity to the process. This autonomy allied to party-political influence allowed the units of the federation, including municipalities, to shape health programmes to a certain extent, according to the local context. The guidelines are sometimes translated into different programmes in each Federative Unit, strengthening the already striking regional differences in Brazil.

The party-political influences lead to lack of continuity and cohesion in work teams. The states with fewer partisan influences showed better results in basic pharmaceutical assistance, which was associated by the interviewees with the continuity and commitment of the teams. The political culture of appointing team members according to election results hinders the continuity that is required to produce incremental gains in public health. This practice also reinforces the lack of commitment that entails, once again, the lack of accountability for pacts governing policy implementation.

The lack of accountability of the entities involved is a recurrent theme when basic pharmaceutical assistance is discussed. The complaints are mainly about the state level. The discussion agenda at the negotiation forums (COSEMS, CIB, and CIT) is focused on transfers of funds due by the state level as part of the co-funding scheme. The subject is too complex and has important repercussions for the public provision of medicines and, as a consequence, has prevented other subjects from reaching the agenda. It is worth noting that complaints about the lack of accountability are directed at the state level of management. The interviewees have acknowledged the consistency of federal funding transfers.

Another element that can be added to this set of arguments concerns the role of coordination and technical assistance that should be played by the state and federal levels. The municipal health secretariats claim, and the TCU report reinforces, that the state level does not play its role in Basic Pharmaceutical Assistance. The state level, with respect to pharmaceutical assistance, is focused on providing high-cost medicines.

Two aspects of the performance of state level in basic pharmaceutical assistance are remarkable. First the political alignments of the state governments influenced the decentralisation process in the area. Second, noncompliance with the covenants, involving financing for the purchase of medicines and the functions of coordination and technical assistance for municipalities, determined the failure or delay in the supply of medicines to the population.

Data from my interviews suggested that the state level plays an essential role in the management of basic pharmaceutical assistance. In the examples of success and failure provided by the interviewees, in both situations, the state level was pointed to as a central piece in the process. However, to date, there are more negative than positive examples, suggesting that the state level is more frequently not playing its role as agreed in the SUS forums.

After having explored the intergovernmental relationships involved in the management of basic pharmaceutical assistance, in the next chapter I will discuss changes in public provision of basic medicines after decentralisation.

## CHAPTER SIX

### BASIC PHARMACEUTICAL ASSISTANCE AND ACCESS TO MEDICINES AFTER DECENTRALISATION<sup>97</sup> (FROM 2005 ONWARDS)

#### 6.1 Introduction

Access to medicines is one of the major concerns of public health policymakers in Brazil as medicines are an important part of health treatment and advances in this field could benefit a large proportion of the population. Improvement in the provision of basic medicines, however, should be considered within the context of primary health care as a whole. The analysis of advances in the Brazilian Health System (SUS) provided by Paim *et al.* (2011) highlights that, despite the difficulties and barriers, SUS has improved access to primary health care over the last two decades. The substantial growth in the number of primary care facilities and the size of the health workforce that followed the creation of SUS in 1988 help to explain the improvements observed. According to the authors, access and use of health services increased significantly after 1988 when SUS was created. In 1981, only 8% of Brazil's total population had used the health service in the previous 30 days, whereas in 2008 the figure increased to 14% in the previous 15 days. Macinko and Lima-Costa (2012) also support these findings about greater access to health services. The authors linked the increase in equity in health care use observed from 1998 to 2008 to the success of national health policies implemented over the period analysed. These advances probably had positive effects on the infant mortality rate,<sup>98</sup> which dropped from 69, in 1970, to 14 per 1,000 live births in 2012.

As discussed in Chapter One, the reform of the health system in Brazil in the 1990s was part of a broad agenda of economic adjustment recommended to Latin American countries by multilateral funding agencies such as the International Monetary Fund and the World Bank. These recommendations for reforms were part of a World Bank document in 1987 which explicitly included decentralisation of services (World Bank, 1987:44). The prominence that decentralisation of the health system achieved in Brazil can be explained as a result of the convergence of interests among foreign funding institutions, the federal government, and the *sanitarista* movement. Regarding the context of pharmaceutical assistance decentralisation, in 1998 Brazil went through

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<sup>97</sup> In this chapter the term decentralisation, unless otherwise specified, refers to the decentralisation of the management of basic pharmaceutical assistance.

<sup>98</sup> The infant mortality rate is the number of deaths of children under one year of age in a year, expressed per 1,000 live births.

another economic crisis that forced the country to take out a loan of \$ 41 billion from the International Monetary Fund. President Fernando Henrique Cardoso, following the neoliberal agenda, privatised many companies that year, and cut funds in the social area. Public spending on health was already dwindling, causing 21% reductions in the budget of health programmes between 1995 and 1998 (Costa, 2002). In this context of this crisis, the economist and Senator Jose Serra<sup>99</sup> took over the Ministry of Health; his administration placed great emphasis on the pharmaceutical field. An important point on Serra's agenda concerned the high prices of medicines, which prompted a major struggle with the pharmaceutical industry.

On the one hand, in this economic crisis, decentralisation was considered a way of sharing by the federal government, with states and municipalities, the responsibilities and the consequent political burden caused by cuts in health funds. On the other hand the *sanitarista* movement and local authorities saw decentralisation as a way to achieve historical goals of empowering local authorities, and to fulfil the specific needs of the regions. With these considerations in mind, we can draw a parallel between the conditions, in the 1990's, which resulted in health reform and consequent decentralisation, and the context of approval of the National Medicines Policy (NMP), which provided for the decentralisation of pharmaceutical assistance.

One of the most important guidelines stipulated in the NMP is the decentralisation of the management of the provision of basic medicines. In my research I asked how the public provision of basic medicines developed after decentralisation of the pharmaceutical assistance. However, it is important to remark that my research is limited to some aspects of the access to medicines and does not include the impacts of decentralisation, if any, on people's health. For instance, it is difficult to isolate advances due to decentralisation from those obtained from the economic development of the country. Even more complicated, in the case of the decentralisation of pharmaceutical assistance, is to disentangle the results of what we could call two steps of decentralisation: the *first step*, the decentralisation of the health system (and the consequent decentralisation of health care); and the *second step*, the decentralisation of pharmaceutical assistance. It is hardly possible to separate the achievements in terms of access due to the decentralisation of pharmaceutical assistance from those due to the development of primary care itself, which followed health decentralisation. Additionally, municipalities and state departments share the same health staff and physical structure to provide primary care and to manage the distribution of medicines. Another confounding factor, which could be associated with advances in access, is the increase in federal funding for primary care

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<sup>99</sup> The increased exposure of the Senator and Ministry of Health is believed to have catapulted him to run for the subsequent presidential elections.

after the *first step* of decentralisation. Those elements corroborate the idea that basic pharmaceutical assistance would face the same difficulties and share the same advances as those experienced by primary care.

Bearing these considerations in mind, in this chapter I will discuss the strengths and flaws of the decentralised management of basic medicine provision, focusing on access. Answering questions on this subject, interviewees provided a rich view of advances and impediments that permeate the process. Initially, in this chapter, I will discuss the positive effects of decentralisation pointed out by interviewees and after that I will explore the issues that decentralisation could not change. I will approach interviewees' perceptions, comparing them with the legal framework and the available data on access.

In order to organise this discussion, this chapter is structured in five sections including this introduction. The second section discusses the structuring of basic pharmaceutical assistance after decentralisation. The third section analyses how access changed following the municipalisation of basic medicine management. The barriers and main failures that have prevented further development of basic pharmaceutical assistance in the decentralised context are the subject of the fourth section. Closing the chapter are the main conclusions.

## **6.2 How was the structuring of Basic Pharmaceutical Assistance enhanced by decentralisation?**

The accounts of my interviewees suggested that changes provided by the creation of the National Medicines Policy (later complemented by the National Pharmaceutical Assistance Policy - NPAP<sup>100</sup>) have caused attention to turn to what municipalities should do in order to manage the provision of basic medicines. Health secretariats, from the creation of SUS onwards, but more intensely after the decentralisation of primary care, claimed that medicines distributed by the federal government did not meet the local needs in terms of diseases, doses and frequency of distribution. My interviewees suggested, as discussed in detail in Chapter Four, that this was a major motivation for them to ask for the decentralisation of the management of drug provision. The NMP has provided the legal support for these changes, but municipalities had to be prepared to respond to the new roles brought by the decentralisation of basic pharmaceutical assistance.

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<sup>100</sup> The context and actors involved in the creation of the NMP and NPAP are discussed in Chapter One, section 1.4.

Although my interviewees pointed out many flaws in activities related to the decentralisation of basic pharmaceutical assistance, the general perception was that decentralisation enabled the structuring of the area in states and municipalities. Interviewees also associate decentralisation with the organisation and strengthening of the pharmaceutical assistance department within the Ministry of Health. Their point of view was grounded in two elements which they portrayed as a consequence of the decentralisation of the sector: the organisation of pharmaceutical assistance activities, including the development of planning routines at municipal level; and the definition of roles and responsibilities of federal, state and municipal level regarding the provision of medicines. The combination of these elements, according to the interviewees, resulted in improvements in the structure of the newly created field of pharmaceutical assistance. I will discuss each of these elements in the subsequent sections.

### **6.2.1 Organising the provision of medicines**

The organisation of pharmaceutical assistance is still a challenge to SUS managers (CONASS, 2011). Organisation, in this case, is a broad term that includes aspects linked to each step of the administration of the pharmaceutical assistance cycle, from the planning to the dispensing of drugs. It means that organising goes from hiring and training human resources to the construction of facilities to store or dispense drugs, i.e. from the administrative structure to the infrastructure. The use of the term structuring, with the same meaning, was frequent in the interviewees' narratives.

My interviewees tended to portray the structuring of pharmaceutical assistance as a consequence of decentralisation. The reasoning underpinning this view was that the definitions of roles, responsibilities, and financing, as well as power distributed to manage and plan the provision, drove the organisation of the pharmaceutical assistance area at municipal and state level. The impetus for structuring and developing the provision of medicines came through decentralised management of pharmaceutical assistance resulting from the NMP, according to my interviewees. The organisation of the activities entailed making medicines available to patients and linking the management of pharmaceutical assistance to the treatments in primary care. These initiatives were driven by the decentralisation process, as illustrated by the next quote:

*I think the strongest aspect of decentralisation is the possibility [the one] of linking the municipal supply of medicines to the demands and to the strategies of treatment used in the primary care level. So, when the manager could make that decision, he [sic] became liable and at the same time the demands started, so the municipality had to be organised to*

*respond to this. So it has generated increased organisation in the municipality to connect what is done in primary care to the decision on which medicines to buy, the quantity needed (Interviewee 18; 7.1).*

From this quote we can see that the changes brought by decentralisation were associated with need (and opportunity) to organise and link the provision of medicines to the strategies of treatment used in primary care. This argument relating decentralisation with the structuring of pharmaceutical assistance at municipalities is disputed by some scholars, who argue that the main focus of the federal government has been the promotion of decentralisation in itself, and less importance has been put on developing the health system infrastructure (Arretche and Marques, 2007). In fact, with decentralisation, state and municipalities took over the responsibility of the management of basic medicines. However, in order to perform their duties accordingly they needed skills and organisation. Taking into account the interviews, it is clear that very little has changed in terms of infrastructure and human resources at the beginning of decentralisation.

Decentralisation transferred responsibilities beyond the dispensing of drugs; however, municipalities did not receive financing to support the structuring of the area. Until 2007, funding was exclusively to buy medicines.<sup>101</sup> From that year, the Ministry of Health changed the regulation, allowing for up to 15% of those resources to be used in the construction of facilities to dispense medication, or with other activities related to pharmaceutical assistance, as voiced by this interviewee:

*The vast majority of municipalities, at least in my state, made a plan for pharmaceutical assistance where they agreed on all these obligations. The pharmaceutical assistance plan also included a policy of rational use of medicines, minimal infrastructure of the pharmacy, storage (...) So following this plan for pharmaceutical assistance we built the structure because an ordinance of the Ministry of Health allows up to 15% resources [of the funds that were previously exclusive to buy medicines] to be invested in structuring pharmaceutical assistance (Interviewee 7; 2.3).*

This meant that although in 1998 there was a significant change in the scope of responsibilities of municipalities and states regarding pharmaceutical assistance, there was no provision of resources to implement these activities. Municipalities should buy and store basic medicines, but until 2007

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<sup>101</sup> The municipalities received the IAFB- Incentivo a Asistencia Farmaceutica Básica or Basic Pharmaceutical Assistance Incentive.

they did not receive funds to build storage facilities and could not hire human resources to plan and execute the procurements. As such, for the population, the supply of medicines did not change soon after decentralisation was implemented. Thus, comparing what should be done according to the legal framework and what in fact municipalities and states received in terms of support and funding, it is not surprising that access to basic medicines remained unchanged in some regions of the country.<sup>102</sup> As I discussed in Chapter Four, the gap between what is provided by the SUS legal framework, and what in fact is implemented in terms of health delivery, is replicated in the case of pharmaceutical assistance. In this example, the NMP stipulated that municipalities would buy medicines according to local demands, but the funds transferred did not allow expenses to develop the structure necessary to put the new roles into practice.

Data from my interviews suggested that not receiving funds to support the infrastructure and human resources contributed to maintaining regional differences. Regions that already had structured and organised primary care engaged and fulfilled their decentralised tasks. The less developed regions, in turn, started the structuring after receiving funds and support from the federal level, which only happened after 2007. Funding issues will be further discussed in section 6.3, when I will detail the barriers to the development of the field.

Building upon the arguments of the structuring as a consequence of decentralisation are the accounts that decentralisation required the development of municipal planning practices to allow for the provision of medicines. In the next quote the interviewee links distribution of power and responsibilities to the need for municipalities to develop management capabilities associated with planning. An important aspect related to planning that appears throughout most of the accounts concerns bottom-up planning, as discussed in Chapter Four, section 4.6. Local initiatives are identified by interviewees as essential to allow the municipal managers to adapt their medicine purchases to the needs of the population residing in the area. The interviewees also linked the need for planning brought about by decentralisation with better performance. The following quote reveals how this obligation shaped the development of the field:

*For example, with decentralisation municipalities had to do planning. We can only buy with planning. We cannot guess the quantities of drugs we should buy. We need to estimate how many hypertensive [patients] there are in the municipality; how they're dispersed within the area of the municipality, to buy the right amount of drugs and distribute them*

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<sup>102</sup> CONASS, in 2011, produced a global analysis of SUS advances and barriers. Within this context, they argued that there is a causal link between the efficiency of pharmaceutical assistance and the organization and structure of the field. Despite these implications, they claimed that federal funding is essentially limited to the purchase of medicines (CONASS, 2011:19).

*among the basic health units. This [need for] planning was introduced by decentralisation. We can only work with planning (...) I think the greatest result of decentralisation was the municipalities being forced to plan (Interviewee 10; 11.2).*

Besides planning, interviewees also highlighted the importance of having adequate medicines for the treatment of prevalent diseases in the area instead of receiving a standard set of medication as was provided by the Ministry of Health before decentralisation.

Interviewees remarked that the insertion of basic pharmaceutical assistance management among the powers of the municipality has made medicines become part of the process of care performed by municipalities. Medication was not a foreign element anymore; it would be part of the process of care tailored according to the needs of patients in the region. In this next quote we can see the association of the decision-making power distributed by decentralisation with better care:

*I think the strong point is the possibility, in the municipality, of an increasingly close linkage between the supply of medicines and the demands (...) So I think what's best is the accountability for all stages of the process: planning, programming, determining how many hypertensive patients we have and how many [drugs] I have to buy ... (Interviewee 18; 7.1).*

Also other aspects merit further attention in these extracts from interviews. Firstly, there is the aspect of 'forced' planning as a result of pharmaceutical assistance decentralisation. Nonetheless, primary care was decentralised previously to the decentralisation in the provision of basic medicines. Both activities require planning, but interviewees argued that it was the pharmaceutical assistance that 'forced' municipalities to plan. It sounds like planning just started after the *second step* of decentralisation. Therefore, it is reasonable to suppose that municipalities suffered from capability constraints that compromised the management of primary care when pharmaceutical assistance was decentralised. This in turn corroborates the accounts discussed in Chapter Four that regional differences in terms of management capability shaped the development of decentralisation, more precisely the views that municipalities in some regions were not equipped to manage the provision of basic medicines. This argument adds another nuance to the explanation about the long-lasting period of implementation of the decentralisation of the provision of drugs also discussed in Chapter Four.

A second aspect that could be explored further is, that - as was discussed in Chapter Four - the freedom to choose which drugs should be purchased was received positively. Such a choice was placed as a counterpoint to the previous policy where a standard set of medication was distributed to all municipalities in the country.<sup>103</sup> Overall, interviewees disapproved the distribution of the same set of medication for all municipalities. That was considered inadequate because the needs of each region are different and depend on the most prevalent diseases in the area. The exercise of this freedom of choice has also brought new responsibilities and the necessity of changing practices to face these tasks. As stated by interviewees, municipal planning regarding the acquisition of medicines was much more a necessity than an option. Despite the fact that ten out of 20 interviewees expressed the importance of planning and scheduling the purchases of drugs, that routine was not implemented, as suggested by the report of the Brazilian Audit Tribunal (TCU) (TCU, 2011). In 2010, as discussed in Chapter Five, TCU inspected 30 municipalities distributed among ten states. It was shown that the schedule of purchases of medicines in the municipalities was inadequate. The inspection's report has indicated that the amount of medicines purchased was based on historical consumption and average monthly consumption. Moreover, data of unmet demand was not registered, i.e. medicines that patients sought but did not find were not included in the programming purchases. Among other problems, the report showed that there was shortage of medicines in all basic health units visited. These data support interviewees' accounts that the legal framework advanced but implementation remained incipient.

In my view, this situation shows the broken link between policy and reality. When talking about pharmaceutical assistance, politicians and managers use what is provided in the legal framework and policy documents to portray the ideal situation for the provision of medicines and access. These documents are used as a signal that things are changing, but in several cases the signal is not translated into actions. The legal framework is also used to create a discourse that confuses what was already implemented in terms of pharmaceutical assistance and what is just part of the legal documents. Sometimes it was hard to understand if the interviewees were talking about what really happens or what *should* happen if the policy had been implemented. This perception of disconnection between discourse and reality, between the legal framework provided by the policy and the actions implemented, will be discussed again in section 6.4.1, within the pharmaceutical care fragmentation topic. This digression on the discourse adopted leads us to the next topic within the structuring process portrayed by interviewees: the new roles and responsibilities derived from decentralisation.

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<sup>103</sup> As discussed in previous chapters, before decentralisation of basic medicine provision the federal government distributed a standard set of 48 medicines to be used in primary care. This initiative was called the Basic Pharmacy Programme.

## 6.2.2 Definition of the roles and responsibilities in the provision of basic medicines

The definition of roles provided by decentralisation required organisation from municipalities and states in order to provide the drugs involved in the primary care. The designation of roles revealed activities that should be performed by municipalities and states. Municipalities, for instance, became responsible for planning and executing activities involved with dispensing medicines. These included the elaboration of a Pharmaceutical Plan detailing what, how many and when to buy; and the corresponding administrative structure responsible for coordinating and implementing these pharmaceutical activities.

The designation of roles within the provision of medicines is emphasised by interviewees as significant for the development of the field. As the interviews suggested, the idea behind those statements appears to be linked to the legal responsibilities of each level. Problems caused by court ruling demanding immediate supply of medicines and frequent failure of the state level in transferring the counterpart funding to basic medicines are examples that help to explain the importance of liability in the decentralised context.<sup>104</sup> In fact, those court cases are part of a phenomenon referred as *judicialisation*, which is an important aspect within the pharmaceutical field, as explained in Chapter Five. Suing the state, the municipality or the federal government to obtain the drug prescribed was a procedure widespread at the end of the 1990s. *Judicialisation* has become very common in many regions of the country and has forced health secretariats to spend large sums to comply with court rulings. Moreover, these unexpected expenditures provided medicines to a reduced number of individuals, contributing to greater inequalities in access. There is no way to argue against or circumvent court rulings, and therefore secretariats had to provide the drugs or officials might even be arrested. Some of the interviewees provided narratives that suggest that the definition of each level's roles was used as a way to improve the accountability of each government level and helped to limit the impacts of judicialisation, as illustrated by these two quotes:

*With the decentralisation [of basic pharmaceutical assistance] the municipal level became obligatorily responsible for providing the set of basic medicines. (...) This meant that we have at least a legal element, written, that [makes clear] the mandatory responsibility of each federal entity (Interviewee 14; 5.1).*

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<sup>104</sup> Failures of the state level in contributing with its counterparts to fund basic medicines and the consequences for access were discussed in more detail in Chapter Five.

*What is positive [regarding the pharmaceutical assistance policy]? ... I think today it is the definition of roles. Municipalities have a role: the [supply of] medicine for primary care is their responsibility. This helped to organise [pharmaceutical] assistance. (...) Today it is very clear in Pharmaceutical Assistance what the responsibilities of each federal entity are (Interviewee 13; 7.1).*

In these accounts the legal assignment of responsibilities to each level that resulted in decentralisation is regarded as a positive aspect of the process. Policy documents and regulations that outlined what should be the role of each level of the federation in relation to the provision of basic medicines are regarded as elements that confer protection in case of lawsuits. This can be understood if we consider that in Brazil, federal, state and municipal levels are responsible for providing different classes of medicines. Medicines that are part of primary care have to be provided and distributed by municipalities. That said, in court cases demanding medicines municipal accountability is limited to the provision of just this class of medicines. It means that patients should not take the municipal level to court to obtain medicines unless those medicines are part of primary care.<sup>105</sup>

As seen in this section, interviewees' accounts suggested that decentralisation of pharmaceutical assistance somewhat advanced the structuring of the field. It is reasonable to suppose that as a consequence of better organisation, access would also improve. The aspects related to the provision of medicines, and whether access developed with decentralisation, are explored in the next section.

### **6.3 Changes in access to basic medicines that followed decentralisation**

Improvement in access to basic medicines was pointed out by 50% of interviewees as the main strength of the current basic pharmaceutical assistance policy. The other half pointed out positive aspects which were also related to access, like planning, improvement in financing and management qualification. In fact, improvement in access is the main purpose of the pharmaceutical assistance policy and all goals are interrelated and interdependent.

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<sup>105</sup> For instance, drugs to treat multiple sclerosis are high-cost drugs, and the responsibility for providing them is shared between the state and federal levels. Therefore, patients demanding medicines to treat multiple sclerosis should sue the federal or state level.

Interviewees suggest that access has improved, particularly after decentralisation. According to interviewees, however, this advance was not sufficient to make medicines available to all people in need. The progress in access achieved is placed in perspective by this municipal health secretary, who drew attention to differences in medicines provided before and after decentralisation. Even if the current coverage did not attain the universal level advocated when SUS started, the advance obtained should be recognised, as explained in the following quote:

*The strongest [point of pharmaceutical assistance] is the access, which increased significantly throughout the national territory, including here in Sao Paulo state. If you think how it was before the pharmaceutical assistance of the SUS, right? We had medicines for tuberculosis, leprosy, childcare and a few more drugs for pre-natal. Today you have a policy of pharmaceutical assistance that few countries have, in the dimension that we have, despite the difficulties ... So, well ... As much as I have criticised [the failures that SUS has], the advance is incomparable (Interviewee 1; 37.1).*

From this quote, besides the changes brought by the pharmaceutical assistance policy, we can also see pride in the scope of the policy, which endorsed universal, free access to medicines for Brazilian citizens: “in the dimension that we have.” The changes introduced by decentralisation regarding the availability of basic medicines will be explored in the two subsections that follow. Firstly I will discuss the accounts related to the positive impacts on access attributed to decentralisation, and then the negative views.

### **6.3.1 Regularity in provision of basic medicines**

Continuous availability of basic medicines, especially drugs to treat hypertension and diabetes, is a positive change reported by the interviewees on the basis of their experiences as secretaries of the state and municipal health departments, although it is not the case in all regions of the country. Interviewees pointed out regularity in the provision of medicines as part of the positive impact of decentralisation, as illustrated by the quote:

*I think the strong point [of the current policy] is that people can make their regular treatment and prevent complications of chronic diseases like diabetes and hypertension.... I think this is the strong point, being able to distribute medicines regularly, free of charge, to [treat] diseases that occur in the municipalities. Many people otherwise would not take the medication because they do not have money to buy it (Interviewee 10; 9.1)*

The interviewee associated the current pharmaceutical policy with the availability of medicines to treat lower-income citizens. We can also see the association of decentralisation with availability of regular treatment and prevention of complications that could result from chronic diseases. It is reasonable to suppose that regular dispensing of drugs means that the steps of planning and purchase have been successfully worked through. Although the interviewee described regularity in provision, it is difficult to demonstrate the improvement in the access reported. There is hardly any national evidence of continuous availability of medicines in municipalities. National studies about access are scarce, and the existing studies employ different methodologies hampering comparability, as discussed in the literature review in Chapter Two. Interviewees have no evidence to corroborate the advances perceived in their work routine. In fact, lacks in monitoring and evaluation of the programmes implemented are significant limitations of basic pharmaceutical assistance, as pointed out by the interviewees, which will be discussed in section 6.4.

Considering studies conducted between 1998 and 2009, regardless of the source of medication being private or public, and the methodological differences, the availability of *essential medicines*<sup>106</sup> ranges from 55% to 96% (Bertoldi *et al.*, 2009; Karnikowski *et al.*, 2004). Even though some studies show reasonable figures in access to essential medicines, it is worth pointing out that the poorest households are those that commit proportionately more income to acquire these essential goods (Aurea *et al.*, 2010). Aurea and colleagues also showed that poorer families, located in the lowest tenth of household income per capita, spend 12% of their monthly cash income on medicines.<sup>107</sup> In the end, the richest families belonging to 10% with the highest income committed only 1.7% of the monetary income. This shows great inequality in income commitment to acquiring medications among income strata. So, failure in public provision of medicines will affect the poorer families more importantly. Aurea *et al.* (2010) argue that SUS pharmaceutical assistance programmes are the main source of medicines in large portions of the population, especially those with lower incomes. The authors show that it is people with lower incomes who benefit the most from free distribution of medicines.

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<sup>106</sup> It is worth elucidating the relationship between essential medicines and basic medicines or medicines that are part of the Basic Pharmaceutical Assistance policy. The National List of Essential Medicines (RENAME) consists of a list of drugs used for treatment of the most prevalent diseases in the country, which are selected considering their safety profile, efficacy, effectiveness and cost-effectiveness. This list guides the supply, prescription and dispensing of medications at SUS services. RENAME constitutes the basic list of medicines funded by the Ministry of Health, so all medicines of Basic Pharmaceutical Assistance are essential medicines, but not all medicines of RENAME are supplied by municipalities. The list can be adapted by states, municipalities and the Federal District according to the population's epidemiological profile.

<sup>107</sup> According to data from the Brazilian Household Budget Survey-POF, 2008-2009 conducted by the Brazilian Institute of Geography and Statistics –IBGE.

Although interviewees felt that overall the improvements and consistency in distribution was a positive development, some of my interviewees and the TCU report pointed in the opposite direction, as I will discuss in the next section.

### **6.3.2 Shortages and a lack of regularity in the distribution of drugs**

The message from interviewees regarding regularity in provision was not consistent. On the one hand, interviewees suggested that medicine shortages are less frequent compared with the times of centralised procurement managed by the Ministry of Health. Moreover, access provided by SUS has reached broad coverage in some areas, such as in the state of Paraná. On the other hand, the majority of interviewees agreed that there is a shortage of drugs in virtually all regions of the country, although it is not possible to pinpoint with certainty where and why the failures continue to occur. The causes may vary from region to region and include failures in public bidding processes, planning (resulting in underestimated purchases), and poor administrative capacity, among others. The following extract from an interview with a municipal health secretary from the São Paulo metropolitan area illustrates that even in the more developed region of the country shortages still happen:

*So, the mayor and municipal health secretariats face shortages [of basic pharmacy medicine] indeed (Interviewee 1; 2.13).*

Another interviewee, speaking about patients from predominantly small rural municipalities, says that there were basically two reasons that explain the low availability of medicines in these locations. The drug prescribed was not part of the list of medicines distributed or the stock was depleted, as illustrated below:

*The doctor prescribes a drug, and even if it is part of the list of the basic pharmacy when the patient asks for it, it is not available. So the stock [of medicines] lasts fifteen days, many [patients] have this complaint. When they go looking for [the prescribed medicine] there is no medicine left and they are sent back [home and have to wait] until the next month. So the main complaint is that either the doctor prescribes a drug that is not part of the list or when they go to the pharmacy it is not available (Interviewee 20; 10.1).*

According to this interviewee there was a common complaint among patients that stocks only lasted for the first 15 days of the month, evidencing planning failures. The unmet needs on medicines are not recorded and therefore will not be part of the planning for the next purchase,

perpetuating the vicious cycle. State and municipal level deficiency in planning is a clear failure, as pointed out in the TCU report mentioned earlier (TCU, 2011).

In states where the basic pharmaceutical assistance is more organised and structured, such as in São Paulo and Minas Gerais, the flaws in the bidding process were held as responsible for temporary shortages. One interviewee from Minas Gerais attributes the main cause for temporary shortages of medicines for primary care to the failures in the bidding process. The alleged flaws in the bidding process might be due to several factors, among them: low administrative capacity, lack of adequate training of human resources, fraud, and lack of interest from the pharmaceutical industry in selling to the state public sector. This last factor has been used more often recently, while opposing the medicines consortium of Paraná against the community pharmacies participating in the Popular Pharmacy Programme.<sup>108</sup>

In general, issues with the procurement process are frequently linked to management capability not only in the health sector. Moreover, public procurement of medicines is a complex and bureaucratic procedure that requires a highly skilled team. This in turn causes more difficulties to small municipalities that usually have small teams with a reduced number of officials that have the specialised skills required to manage a complex public procurement process. Therefore, even in more developed states of the federation, which have reached good levels of access to medicines, some barriers could not be removed and interruptions arose in the provision.

After discussing the main features of the pharmaceutical assistance that emerged with decentralisation, the next section will present the main barriers that interviewees held responsible for hampering further advances in the field.

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<sup>108</sup> This argument was raised twice during a public hearing to discuss the Popular Pharmacy Programme in the Chamber of Deputies in October 2012. Managers of the Paraná Health Consortium reported that from 2011 to 2012, they had more difficulty acquiring some basic medicines for pharmacies, and that the prices have increased. It is speculated that this is due to the Popular Pharmacy Programme. It is believed that the pharmaceutical industry prefers to sell to pharmacies participating in the Programme because of the bigger amount purchased and better prices paid by the federal government for drugs distributed by the Programme. Available at: [http://www.crfpa.org.br/sitesed/crfpa/?tipo=conteudos\\_site&tipo\\_conteudo=noticia&tipo\\_consulta=v&id=3689622056340109](http://www.crfpa.org.br/sitesed/crfpa/?tipo=conteudos_site&tipo_conteudo=noticia&tipo_consulta=v&id=3689622056340109) [last accessed 24/07/2013]

The Popular Pharmacy programme will be discussed in depth in Chapter Seven.

## **6.4 Barriers to progress**

As mentioned in Chapter Four, according to the interviewees, decentralisation of basic pharmaceutical assistance was an expected development of the decentralisation of health care. As the interviewees stated, they expected to have control over the management of provision of basic medicines after municipalisation of primary health, because of the importance of medications for therapy. However, the transfer of these additional responsibilities and powers to manage the provision of medicines was not easily translated into services. Decentralisation of pharmaceutical assistance management put municipalities in charge of all steps involved in the distribution of basic medicines, but pharmaceutical assistance did not develop as foreseen in the NMP. My interviews suggest that the characteristics of decentralisation itself and SUS context hampered progress. State and municipal actors had difficulties with implementation, but more notably at municipal level, where management capabilities were often less developed.

Overall, the message in all the interviews is ambivalent. The interviewees started discussing advances in pharmaceutical assistance and turned to problems and barriers. Usually each strong point was followed by an account of a negative aspect. This section brings together the aspects that interviewees considered the main weaknesses of basic pharmaceutical assistance policy. Moreover, the difficulties with planning and shortages already discussed, the main failures and barriers highlighted throughout the interviews, are related to policy fragmentation; lack of integration between the distribution of medicines and care; insufficient funding; low management capacity; and the absence of mechanisms and indicators for monitoring and evaluating the policies implemented. According to the interviews, these drawbacks prevented the pharmaceutical assistance from fulfilling the goals provided in the NMP. In order to better understand how this happened, the main barriers pointed out by interviewees are discussed below in four subsections.

### **6.4.1 The fragmentation of Pharmaceutical Care**

Health service fragmentation is considered a serious problem in Latin America and the Caribbean (PAHO, 2010).<sup>109</sup> Even though the idea of comprehensive health services has been ubiquitous since SUS was created, care is still fragmented within the system. As this interviewee argued, the model of care adopted in SUS led to health care fragmentation and pharmaceutical assistance followed the same pattern:

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<sup>109</sup> PAHO defines health service fragmentation as health facilities and services at different levels of care that are not coordinated among themselves or that do not provide care over time; health services that do not cover the entire range of promotion, prevention, diagnosis, treatment, rehabilitation and palliative care services; and services that do not meet people's needs (PAHO 2011).

*The issue of fragmentation of SUS policies is an inheritance [that persists from before SUS creation in 1988] that we have. It is the consequence of the way that, historically, health policies were implemented in Brazil. (...) I would say to you that fragmentation is not unique to pharmaceutical assistance. This fragmentation is [a result] of the management of care, of the model of care that we have that is still symptom-driven (Interviewee 1; 21.2).*

The interviewee ascribed the fragmentation of pharmaceutical assistance to the model of care centred on disease and acute care adopted by SUS. The interviewee referred to the traditional health care model designed to provide symptom-based responses to acute illnesses. Although SUS policy documents indicate changes toward a comprehensive model that integrates promotion, prevention and health care, the symptom driven model is still in practice in SUS according to the interviewee.

This assessment is corroborated by scholars who argue that health systems in the Americas are characterised by high levels of fragmentation, and that the model of care is one of the leading causes of this phenomenon (Montenegro *et al.*, 2011). The fragmentation of SUS manifests itself in different ways, but mainly as weaknesses in links between the management system and health services, and as disconnection between the health services and support services for diagnosis and therapy. Fragmentation jeopardises the care offered, hindering users' access to services and causing loss of continuity in care (PAHO, 2010). Similarly to what occurs in primary care, basic pharmaceutical assistance policy and services are fragmented. This feature undermines care delivery, hindering access to medicines and services. Brazilian health secretaries also manifested their discontentment with the fragmentation of pharmaceutical assistance, and identified the model of care used in SUS, driven by disease, as the origin of the problem (CONASS, 2011). The system is considered fragmented because different sectors within the Ministry of Health are responsible for activities that interfere with the provision of medications. Some of the activities are overlapped, replicated and uncoordinated. This fragmentation has historical roots in the organisation of pharmaceutical services within the Ministry of Health.<sup>110</sup> To illustrate this fragmentation I will use the example of medicines to treat diabetes and hypertension.

The Department of Pharmaceutical Assistance (DPA) manages basic pharmaceutical assistance at the federal level. This sector coordinates the agreement process and funding, which results in the

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<sup>110</sup> Until 1997 the Centre for Medicines (CEME – *Central de Medicamentos*) centralised all activities related to medicines. Deactivation of CEME caused its responsibilities to be reallocated to different departments within the Ministry of Health (Cosendey *et al.*, 2000).

rules governing the process involved in public provision of medicines. Funds to purchase hypertensive and diabetes drugs are transferred by the Ministry of Health to state and municipal health funds. They, in turn, give their contribution (co-financing) and are responsible for the purchase and distribution of the drugs. But in the case of insulin, which is also part of diabetes treatment, the purchase is made directly by the federal level. Municipalities estimate the quantity of medicines necessary, using data from a database of patients with hypertension and diabetes called HIPERDIA (Hypertension and Diabetes Programme), which is coordinated by the National Coordination of Diabetes and Hypertension, which is not part of the DPA. Moreover, the purchase of supplies for diabetic patients, such as syringes, needles and blood glucose strips, is the responsibility of states and municipalities. Thus, SUS patients with diabetes receiving treatment cannot imagine the complex sequence of events that must happen before medicines can be dispensed as needed. There is a combination of centralised and decentralised efforts occurring in different areas of the Ministry of Health without unified coordination at the federal level. If within the Ministry of Health the actions are divided among different areas, patients will also have to search in more than one location for treatment.

In another example, if a child is diagnosed with pneumonia in an emergency care unit, his/her parents will not get the medication from this health service to continue the treatment of pneumonia diagnosed. They will need to go to a basic health unit the next day to have an appointment with the doctor in order to receive the prescription. Only after going through this process will they qualify to receive the medicine although the child had just been diagnosed in a SUS facility, by SUS doctors. Likewise, when diabetic patients are attended in the emergency service they do not receive drugs to continue the treatment at home, but have to make an appointment with another doctor.

Like health care, pharmaceutical assistance shares the same difficulties in terms of health service integration as other SUS services. Medical training is singled out as a significant barrier to the integration of services (Harris *et al.*, 2007). Medical schools has been putting more emphasis on training specialties at the expense of medical generalists and this strategy is believed to drive professionals to build a private career. That in turn leads medical doctors to multi-employment in the private and public sectors, resulting in excessive workload (Feuerweker, 2001). These external obligations are considered to weaken doctors' commitment to the municipal health service (Harris *et al.*, 2007). The Family Health Programme illustrates the influence of doctors in integration of care. This programme is a community-based primary care service at the municipal level and, despite being a successful initiative, has patchy integration with specialist services (Harris and

Haines, 2010). The referral system to the specialist and the communication between generalist and specialist is still deficient, compromising the continuity of patients' treatment.

Fragmentation is not limited to aspects of management and provision of services. Actually, the way the transfers of federal funds are organised is argued to be the cause of the fragmentation in the first place (Santos, 2007). The financing strategy adopted for funding medicines has contributed to creating and maintaining fragmentation. Pharmaceutical assistance is divided into three categories called components (basic, specialised and strategic) and each has specific funding. Moneys are labelled for purchase of specific medications, and this makes specific programmes be developed for the distribution of certain drugs. In addition to the lack of integration of health services within SUS the provision of medicines is not integrated to health services as it should be. For instance, the Ministry of Health had various programmes that separately financed the purchase of diabetes and hypertension drugs. The provision of drugs for the treatment of diabetes and hypertension has been the subject of frequent government programmes given the significant number of patients in the population in all regions of the country. This subject of programmes has changed and now the money for primary care medicines is all gathered in one source. But sources remain separate in relation to the components of pharmaceutical assistance. The funds are earmarked for the purchase of a certain component, so they cannot be used to purchase other types of medicine, even if there are unused funds for one component. The following quote exemplifies how fragmented the provision of drugs was before decentralisation, when the federal level used to have multiple initiatives to provide the same class of drug:

*(...)Hypertension and diabetes medication were part of the list of drugs that municipalities had to purchase, they already were part of the pharmaceutical assistance [Ministerial] Orders, and the Ministry had until that moment [before the decentralisation] parallel programmes, such as HIPERDIA<sup>111</sup> for example. Then, you had hypertension and diabetes drugs in HIPERDIA, in Women's Health, in the Health Penitentiary [programmes]... So, we had several offers for the same drug in separate programmes with separate funding, which usually did not reach all people [in need] (Interviewee 13; 4.1).*

The programmes were considered parallel initiatives because they worked independently without central coordination. To a certain extent, regarding primary care medicines, financing was unified but the supply of medicines for diabetes and hypertension remained scattered within different programmes. Despite having been dispensed by basic health units these drugs are currently

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<sup>111</sup> HIPERDIA is a system of registration and monitoring of SUS patients with hypertension and diabetes.

included in the Popular Pharmacy Programme, at the national level, as I will show in Chapter Seven.

#### **6.4.2 Lack of integration between the distribution of medicines and care**

The lack of integration between care and provision of medicines is a concern evidenced in most of the interviews. Deficiencies in monitoring and evaluation of the system as well as weak management capability are cited among the barriers on care integration (Montenegro *et al.*, 2011). State health secretaries argue that, in Brazil, medicines are still considered as something separate from the health service, discouraging the integration of pharmaceutical assistance into primary care (CONASS, 2011:25). Pharmaceutical assistance as planned in the NPPA is far from being achieved, as one municipal secretary from the metropolitan region of Sao Paulo says:

*The Ministry of Health is still quite fragmented. So the various areas within the Ministry did not talk to each other. So the creation of the National Policy on Pharmaceutical Assistance and this integration effort with the assistance areas, I think that is still ongoing in the Ministry of Health. It is a question that is not yet resolved. But I think it will take 10 years to enter the political agenda in the same way as other important areas took (Interviewee 8; 4.1).*

Overall, my interviewees were emphatic in separating the advances in terms of availability of medicines and pharmaceutical assistance itself. They make it clear that access has improved, but that the care did not follow this advance. In the next extract the interviewee believes that, currently, only when patients are hospitalised do they get pharmaceutical assistance as it should be:

*And I'm really emphasizing the question of access, because for me one thing is access to medicine, another thing is effective pharmaceutical assistance. They are two separate things. So I think in relation to the access point there were some advances, but in terms of pharmaceutical care it is almost zero. Today the little pharmaceutical assistance that we have in SUS, in my view, takes place in hospitals where there are qualified and trained staff, and where there are defined policies and actions aiming to achieve qualified pharmaceutical attention. But today we have a situation where, occasionally, we get some progress on access to medicines, but in terms of pharmaceutical care as a whole, I think that, unfortunately, SUS has advanced on nearly nothing. I'm quite sure about this (Interviewee 17; 3.2).*

As the interviewee stated, activities other than dispensing of drugs are not yet implemented in primary care. Activities to promote the rational use of medicines, like counselling on the appropriate use and potential risks of medications, importance of taking drugs as prescribed to enhance medication adherence, and quality assurance of drugs dispensed are not part of the pharmaceutical service routine.

Pharmaceutical assistance is not included in the planning of the departments of health, and this makes it difficult for pharmaceutical assistance services to participate in health activities in states and municipalities, as highlighted by CONASS (2011). This can be evidenced, for example, in drug prescriptions. According to the NMP and NPAP, prescribed drugs should be part of the RENAME list, but doctors are not trained for this, and the observance of the prescription rules is not enforced. The fact is that many SUS doctors prescribe drugs that are not part of the municipal medicines list. Thus, patients treated by these doctors have two alternatives: pay for drugs out of their own pockets or take the municipality to court. This practice undermines the whole logic that governs basic pharmaceutical assistance. Although, in my opinion, prescription practice is an important aspect to understand the barriers pharmaceutical assistance has to overcome in order to be implemented, interviewees did not in general talk about it. A plausible explanation for this lack of interest in discussing this subject could be that many of these interviewees are medical doctors and are not comfortable discussing their peers' behaviour.

Policy fragmentation and the lack of integration between provision of drugs and care are connected topics and reinforce the negative effects mutually, and both were associated by my interviewees with loss of efficiency in pharmaceutical assistance.

### **6.4.3 Funding**

In order to understand the interviewees' claims about funding schemes, it is helpful to have an overview of the SUS funding and more particularly about medicines. Underfunding of health has been part of an intense debate among health secretaries since 2003 (CONASS, 2011). In 2000, an amendment to the Constitution, Constitutional Amendment 29 - EC-29, defined minimum limits for spending on health in the spheres of government and also established sanctions in case of noncompliance with the minimum limits. According to EC-29, the Union must spend on health the same amount of money committed in the previous year, adjusted by the variation of nominal GDP between the two previous years. States must spend on health 12% of the amount of taxes collected, and municipalities 15% of their own taxes.

Since 2000, state and municipal authorities have complained that the federal level, which is the largest tax collector, should spend more on health. In their views, a fixed minimum percentage of health expenses should be established, as was done with states and municipalities. The fact is, however, that the federal government spent 7.3% of the current gross revenue on health in 2011, whereas it spent 11.7% in 1995.<sup>112</sup> EC-29 was regulated in 2011 and CONASS, CONASEMS, CNS and the Health Conferences supported the proposal that the Union should spend a minimum of 10% of current gross revenue. The federal government, however, lobbied for its rejection in the Senate, arguing that this would mean an increase in annual expenditures of approximately R\$ 30 billion (around £10 billion) and that there were no resources available. Thus, the federal spending continues, to this day, to have no connection with the collection of taxes. Instead, it is bound to expenses incurred in the previous year. This means that the largest share of investments originates from the states and municipalities. In fact, the largest share of public spending on health, 53%, has its origins in the states and municipalities while the federal level, despite being the largest fundraiser, brings 47% (Carvalho, 2012).

This federal underfunding has predictable consequences in the area of pharmaceutical assistance, and among the difficulties pointed out by state and municipal secretaries are the rising cost of drugs and their impact on the health budget. The following extract from an interview with a state secretary reveals the effects of health underfunding for the performance of pharmaceutical assistance:

*[The availability of medicines] just does not advance anymore because there is no [financial] resource to support it. It was a sector that was left behind in the past, but advanced a lot, especially in recent years. The list of medication was increased, the pacts were expanded, resources were expanded, but still not as fast as the cost, demands, and technology have advanced. I believe that if this [financial] resource grew as spending did we'd be [doing] better. But I have no doubt that we advanced (Interviewee 2; 14.1).*

The interviewee suggests that the provision of drugs has advanced but further developments have been restrained by insufficient funding in order to cope with rising costs due to increased demand and technological advancements. This underfunding of health, despite being a common complaint among virtually all SUS managers, whether they are interviewees in this study or managers who

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<sup>112</sup> Current gross revenue is the money received from taxation, fees, fines, and any sales that are made. It is the gross income without credit and capital gains.

appear on TV or in the newspapers talking about health in Brazil, is a disputed view between my interviewees.

The secretary of health of a municipality in the southern region of the country affirms that the amount of money available for basic pharmaceutical assistance is enough to supply the population with the necessary medicines since the process is well managed and there are no purchases of brand-name drugs.

*I can say that the resources available today are sufficient to meet basic pharmaceutical assistance, without major capital expenditures. (...) So we tried to make sure that medicines acquired have quality, [the medicines are] approved by ANVISA,<sup>113</sup> comply with all legal requirements in public procurement processes ... But we work with certain types of analgesics, anti-hypertensive, etc. [We work] with several of them, we do not use only one [specific type of brand-name medicine]. But none of these are the latest releases of the market. No, they are not (Interviewee 7; 3.3).*

The example suggests that having administrative capacity to plan and bid to purchase generic medicines is critical in the use of available resources. Accounts from interviewees suggest that it is precisely this difference in administrative capacity which allowed certain regions to adjust to decentralised management of provision of medicine better than others.

There is still one more element cited by a Ministry of Health official that corroborates the view that financing available today for pharmaceutical assistance is sufficient in certain regions. This interviewee mentioned a meeting of CIT (Tripartite Intergovernmental Commission) that reported that there were pharmaceutical assistance funds left and they should decide what to do with them:

*Resources are sufficient? Resources are insufficient? At the beginning of the past decade, we were certain that money was insufficient. Today, I've seen discussions in CIT that there is some money unused; I don't know where. They had to decide what to do with this financial resource. So, funds are no longer insufficient in all Brazil, but also they are not more than sufficient all over Brazil (Interviewee 18; 8.2).*

As the moneys for pharmaceutical assistance are earmarked, health secretariats need permission to use the money left. A possible explanation for the unused funds could be, as the interviewee said,

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<sup>113</sup> ANVISA is the Brazilian Health Surveillance Agency, the agency responsible for drug registration.

that the amount of money available to buy medicines is more than sufficient in certain regions. I did not find data to support this and many of my interviewees clearly signal the contrary. In fact, only two out of 20 interviewees disagree with the general view that funding is still an issue in pharmaceutical assistance. In general, interviewees suggested that money was not sufficient to buy adequate quantities of medicines. This position is corroborated by the TCU report that showed a shortage of basic medicines in all the 30 health units audited in 2010 (TCU, 2011). In my opinion, unused funds could be better explained by inadequate estimates of demand, as a result of poor administrative capacity, to conduct medicine bidding processes, along with lack of planning strategies. However, in order to determine the causes of these surpluses of funds more research is needed and it is not within the scope of the present work.

Overall, twelve interviewees mentioned underfunding as a significant barrier and of them six claimed that the federal funding for structuring of pharmaceutical assistance has not yet reached the necessary level to provide municipalities with means to fulfil their responsibilities in the field. Different solutions, depending on state initiatives, were implemented in order solve the issues related to the lack of suitable infrastructure. An example of how the question has been addressed regionally comes from Minas Gerais. In 2008, the state health secretary supported a programme to construct a network of public pharmacies using a state financial incentive (Guerra Jr, 2012). The *Farmácia de Minas* programme includes the construction and structuring of 1248 SUS pharmacies distributed over the totality of all the 853 municipalities in the state.<sup>114</sup> The programme also provides a transfer of financial incentive for pharmaceutical procurement and the establishment of a process of continuing education for human resources. The results of this initiative are appreciated by municipal health secretaries, as shown in this quote:

*In Minas we decided, using state funds, to construct basic pharmacies. Today 60% of the municipalities in the state have their basic pharmacy built. It is a complete pharmacy, with all the facilities that are required. It has adequate storage area; and has a special room for pharmaceutical attention, which is no longer just a counter in a corridor. Minas has succeeded with this project so well that many municipalities using these pharmacies started delivering actual pharmaceutical assistance, not simply drug delivery (Interviewee 6; 14.1).*

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<sup>114</sup> *Farmácia de Minas* means ‘Pharmacy of Minas’. The initiative is part of the State Plan for Structuring Pharmaceutical Assistance. Municipalities receive from the State Treasury an incentive for construction of the pharmacy and purchase of equipments. Moreover, a monthly amount is sent to the municipality to supplement the salary of the pharmacist responsible for the unit. According to the webpage of state health secretary of Minas Gerais, in May 2013, there were 503 units of the programme. Available at:

<http://www.saude.mg.gov.br/component/gmg/page/350-farmacias-inauguradas-sesmg> [last accessed 24/07/2013]

Besides this initiative, Bahia state also implemented a similar programme. In 2009, the state launched its own initiative and constructed pharmacies in municipalities with fewer than 30,000 inhabitants. As in Minas Gerais the money to develop the infrastructure came from the state fund.

These programmes, as interviewees suggested, were a sign of the need to improve the infrastructure of pharmaceutical assistance. Perhaps in response to pressures for specific funding, from 2010, the federal government allowed up to 15% of state and local counterparts to be applied in the structuring of pharmaceutical assistance in Primary Care (Ministerio da Saude, 2009a). These funds are regarded as an important step. However, in 2011, when I conducted the interviews, the results of the application for these funds had not yet been assessed by the interviewees.

#### **6.4.4 Regional disparities reflected in differences in pharmaceutical assistance development**

I discussed regional differences in the implementation of decentralisation in Chapter Four and now I will reflect on how these differences have influenced users' access to drugs in different regions of Brazil. Interviews suggested that regional differences are associated with factors and circumstances that did not change with decentralisation. In other words, differences are associated with things that decentralisation has not been able to change. The issue of lack of technical support and training for municipalities is a clear example. The regional pattern of health development is replicated in terms of pharmaceutical assistance. So, the interviewees described different realities in terms of access depending on the region. Minas Gerais state, as described in the quote that follows, made significant progress and now is able to provide the population with basic medicines on a regular basis:

*So, the strong point is the improvement in access to the list of basic medicines. We have to think that within the basic list of Minas we have about 180 items, which in our view, meets the minimum requirements of 80% of the population. So, medicine is [sufficient] to meet the entire demand of the municipality. The main fault occurs in bidding, which causes shortages. But usually we're ensuring [access to] the basic medication list (Interviewee 6; 8.2).*

As voiced by the interviewee, in Minas Gerais the provision of medicines for primary care was organised and the population has access to basic medicines. This means that the planning and choice about which medicines to buy and facilities for storage and dispensing were already achieved. The problem reported by the municipal health secretary is related to the procurement

process which under state level responsibility in Minas Gerais. The interviewee connected procurement flaws with the logistics failures in distribution to municipalities, which cause shortages of medicines. Logistic issues are part of Brazilian life. In this case, they are related to the private sector, which is in charge of the distribution of basic medicines bought by the state to supply the municipalities. The failure here is not seen, by the interviewee, as a limitation on the ability of the state to deal with the management of drug supply.

Another aspect that corroborates the account of the interviewee on progress in pharmaceutical assistance in Minas Gerais relates to implementation of the *Farmácia de Minas*. However, the emergence of this programme also suggests, in my view, that provision of basic medicines is still under development and universal coverage has not been reached. Even developed regions such as Minas Gerais where the state level plays an active role in the coordination of pharmaceutical assistance can benefit from programmes such as *Farmácia de Minas* to increase the access to medicines.

Consistency in the availability of medicine as experienced in Minas Gerais is not a reality in other regions of the country. In Amazonas state<sup>115</sup> the purchase of medicines for primary care is a municipal duty. A precarious situation regarding availability of medicines is described by a municipal health secretary in the region:

*Municipalities have difficulties making purchases ... First because of the costs...Moreover, access to municipalities is complicated by the issue of transportation. Everything is by boat or by air. Where I live the municipality is not connected [to other parts of Amazonas state] by road. There are very few municipalities in the state that are connected by road, so the distribution of medicines is very complicated (Interviewee 16; 3.2.).*

In the Amazon region, small municipalities, on top of the usual issues of poor administrative capability, as discussed in Chapter Four, have infrastructure problems related to the supply chain of medicines. Environmental characteristics add complexity to daily activities, as the interviewee described. So it is reasonable to think that municipalities in the Amazon region have more difficulties managing the provision of basic medicines than in Minas Gerais, for example, and would require more support from state and federal levels. As my interviews suggested, as well as these unfavourable geographic characteristics, municipalities in Amazonas do not have support from the state administration with regard to the development of pharmaceutical assistance. Support

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<sup>115</sup> Amazonas state covers 1,570,745.68 km<sup>2</sup>; it is bigger than the UK, Spain and France together.

and training are amongst the responsibilities assigned to the state level. How things really happen in that region is well illustrated in the next quote, where a municipal health secretary from the Amazon region described in which circumstances his/her legal obligations regarding provision of medicines were unveiled and how the lack of management training was remedied:

*When I arrived in the municipality - I am a nurse - I really had no experience. I had to learn [what I should be doing] when I received an audit from the CGU.<sup>116</sup> After that I searched for what they observed. That was when I really knew how pharmaceutical assistance should be. Then I started to worry because we have no management training. The Secretaries of Health are chosen more for political indication, although in my case it was not so. So that's how I started learning and then I had an audit course where I learned what we must do (...) I think the state [level] should play its role along with the municipalities. We never, ever received such technical assistance or training to manage the provision (Interviewee 16; 9.2).*

In Amazonas, it is clear that neither the federal nor the state level fulfilled the role of coordinating or technically supporting municipalities, to allow for the development of the skills needed to choose the appropriate medicines and the adequate quantities and all activities involved in the procurement, distribution, storage and dispensing of medicines. Instead, in the example above, the municipal health secretary took an audit course to learn how pharmaceutical assistance in the municipality should be. The CGU, which is not part of the health system, trained the municipal manager when in current regulations, the Ministry of Health and the state level should provide management training for municipal officials.<sup>117</sup> From this example, it is clear that differences in terms of management capacity at both state and municipal levels have significant impacts on the provision of medicines.

This lack of support certainly impacts the access to medicines and to health services. Infant mortality, which among other factors reflects the characteristics of health systems, in Minas Gerais and Amazonas follow the pattern of pharmaceutical assistance described by interviewees. Amazonas shows worse infant mortality rates when compared to Minas Gerais.<sup>118</sup> The economic level of development of each region determines the corresponding health development level which,

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<sup>116</sup> CGU - Office of the Comptroller General

<sup>117</sup> This lack of coordination in state and federal levels is discussed in Chapter Five. The assessment of failure in coordination is reinforced by the TCU report on the evaluation of SUS basic pharmacy conducted in ten states in 2009.

<sup>118</sup> Minas state's infant mortality rate in 2010 was 16.2 per 1,000 live births; while Amazonas showed 20.6.

in turn, seems to be linked to the level of pharmaceutical assistance in the region. My interviews suggested that decentralisation of pharmaceutical assistance was not able to change these regional disparities in terms of access to basic medicines.

#### **6.4.5 Low management capability**

The changes introduced by decentralisation precipitated the need for municipalities to develop management capability. For instance, according to the current policy, the decision on what and how many doses of medicines to buy is a municipal task even when the bidding and payment are done at the state level.<sup>119</sup> The municipality has to decide which medications are appropriate and the schedule of purchases. The NMP stipulated that these decisions require the elaboration of a pharmaceutical assistance plan made by a specially appointed committee. However, according to the TCU report on SUS basic pharmaceutical assistance, 56% of the 30 municipalities visited do not have a pharmaceutical assistance plan and 70% do not have pharmaceutical committee (TCU, 2011). The lack of qualified human resources is one of the justifications of the municipalities for these failures.

Corroborating TCU's findings are the interviewees' accounts that associated the lack of a coordinated training of SUS manpower with the difficulties in implementing pharmaceutical policy. Interviewees stated that workers should have a SUS career, as occurs with other areas of public service, such as juridical careers. They advocated that the Ministry of Health should lead changes in the health education field in order to provide SUS with qualified human resources, and especially for pharmaceutical assistance. The following extract from an interview with a municipal health secretary is a good example of the responses obtained about this aspect of human resources:

*We have two problems; one is the formation of professionals for SUS. We do not have a policy of human resources training. We do not have a SUS career as exists in other sectors such as the judicial branches, and this causes great difficulty for public policy. Ideally we should have a SUS career but we do not have, it would be ideal to advance in the training of more professionals for SUS (Interviewee 2; 17.1).*

Administrative problems are aggravated by this lack of human resources training focused on SUS needs. The mismatch between the goals set by the policy framework and qualification of human

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<sup>119</sup> Municipalities, as discussed in Chapter Five, could opt out of complete decentralisation leaving to the state level the task of acquiring basic medicines. How this option of decentralisation works is explained in detail in Chapter Five.

resources available is clear in the statement that follows. The interviewee, an official of the Ministry of Health, is sceptical when commenting on the managerial capacity of municipalities to perform pharmaceutical assistance as required by national policy:

*Management is still our weak point, I think. When we think of the cycle of pharmaceutical assistance, even if you consider that the proposed cycle is a bit out of date, plan programming, acquisition and distribution, they are still a major challenge to municipalities. [We need to] have people trained to operate this cycle. So when we talk about qualifying access, promoting rational use, etc ... we still cannot resolve [the issue of human resources training], and do not have people trained to operate the cycle in many municipalities (Interviewee 19; 7.2).*

The same official is even more explicit about the degree of unpreparedness of the people who have responsibility for managing pharmaceutical assistance, regarding two specific regions of the country:

*We did not yet manage to solve this issue of having people trained to operate the cycle [of pharmaceutical assistance] in the municipalities. (...)I am frequently in contact with the situation in the Northern and Northeastern regions of the country. There, people, in most cases, are unaware of the process [of management of basic pharmaceutical assistance]. It is still shocking for us (Interviewee 19; 7.1).*

This account reinforces my argument that reality is still far from pharmaceutical assistance as set out in the legal framework. Poor administrative capability is a common criticism of SUS and other services in Brazil, and in other developing countries (Ferreira, 2004). In Brazil, although deficiencies in management are frequently used to hide other failures, and are part of the arguments in favour of privatisation, they are significant obstacles for the implementation of the pharmaceutical assistance policy, as my interviews suggested.

#### **6.4.6 Absence of tools and indicators for monitoring the implemented policies, and the alternatives to estimate access**

Another major flaw that constitutes an obstacle to progress in access to medicines is the monitoring and evaluation of pharmaceutical assistance. Six out of 20 interviewees pointed out that the absence of national databases with records on monitoring, evaluation and indicators hindered assessment of the performance of basic pharmaceutical assistance and made improvement difficult.

Before discussing interviewees' accounts I shall give an overview of the monitoring situation within SUS.

In 2010, as mentioned before, TCU conducted an audit to analyse the implementation of basic pharmaceutical assistance by the three levels of the federation, evaluating the efficiency in resource management by state and municipal entities and the controls carried out by the Ministry of Health (TCU, 2011). The TCU report made it clear that the Ministry of Health does not monitor or evaluate basic pharmaceutical assistance. The auditors are categorical in stating that the Ministry of Health has no indicators to assess the performance of pharmaceutical assistance programmes. In fact, the audits of the boards of control<sup>120</sup> represent the most comprehensive source of information on basic pharmaceutical assistance available today. The Ministry of Health has been required to submit performance indicators to assess the basic pharmaceutical assistance on at least three separate occasions between the years 2008 and 2010. However, to date these indicators have not yet been implemented. Also according to the TCU, even if those indicators had been proposed they could not have been calculated because states and municipalities do not send the required data to the Department of Pharmaceutical Assistance (DAF). Until 2007, DAF had a database with compulsory input, called Sifab, whose main function was financial control, enabling the monitoring of the resources used in basic pharmaceutical assistance.<sup>121</sup> According to DAF, Sifab was abandoned because it was inadequate to the needs of the managers of the three spheres. Hence, in 2009, the Ministry launched HORUS, designed to assist the management of pharmaceutical care, replacing Sifab.<sup>122</sup> The HORUS database would also provide information to evaluate the performance of the programme, such as medications dispensed, population served, unmet demand, origin of the prescription, and resources applied, among others. However, HORUS does not have mandatory data-feeding, so municipalities can choose whether or not to send the information to the system. Moreover, many municipalities already have their own systems, so the implementation of HORUS and its integration with the existing systems was jeopardised and will require effort and significant time, as illustrated in the following quote:

*We took two and a half years to get 170 health units, and are still begging for health secretariats to use the system [HORUS] ... So it's quite different [from the private sector]. The public [sector] feedback is very time consuming (Interviewee 19; 11.2).*

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<sup>120</sup> The national boards of control are TCU and CGU- Office of the Comptroller General. SUS also has an internal board of control, DENASUS - National Department of Audits of SUS.

<sup>121</sup> Sifab was the Basic Pharmaceutical Assistance Resource Incentive Monitoring System.

<sup>122</sup> HORUS is software to manage pharmaceutical assistance designed by the Ministry of Health which allows the control and distribution of medicines covered by SUS.

This interviewee, who worked in the implementation of HORUS, reveals how negotiation to convince municipalities to join the system is laborious and time consuming. As discussed in Chapter Five, decentralisation provided an opportunity for local solutions to be found; however, as stated by this interviewee, autonomy also brings slowness and lack of standards as reported in the case of the databanks. Yet, as regards the lack of assessment of pharmaceutical policies, the Ministry of Health commissioned two national surveys whose preliminary results will be available in December 2013. One is to assess the basic pharmacy and the other to evaluate the Popular Pharmacy Programme. The following quote illustrates how poor the data available on access currently are:

*You asked me what I would say to the Minister about access to basic medicines provided by pharmaceutical assistance in SUS. I would have nothing to say. (...) About SUS I can't say anything. I do not have any data from SUS. The system HIPERDIA, I do not have much to tell you because it is managed by the co-ordination of hypertension and diabetes. (...). Anyway, like all SUS information systems it has its difficulties of input, but ultimately these are the data we have about SUS. The data are not robust and that's why nobody speaks of them [the data] (Interviewee 19; 11.2).*

Deficiencies in monitoring pharmaceutical assistance, as clearly pictured by this official, place the Ministry of Health in a vulnerable position. There are no data to inform decisions on what should be tackled to implement effective provision. The federal level should be able to monitor if patients are receiving the medicines they need. But interviewees and TCU audit data suggest that despite being crucial for management, the implementation of a national system to record and monitor the performance of pharmaceutical assistance is a complex task.

The WHO presents a series of indicators of structure, process and outcomes to assist the monitoring and evaluation of drug policies (WHO, 1999). A comprehensive study on the situation of pharmaceutical assistance in Brazil using the indicators proposed by the WHO was carried out in 2004 (Marin Jaramillo *et al.*, 2005).<sup>123</sup> Regarding access, 74% of the drugs were available free of charge at public facilities. These data match the situation of public provision of basic medicines before the effective decentralisation of the area in 2004. That was the access level that decentralisation of pharmaceutical assistance policy was supposed to improve. So far there are no national studies that show improvement in coverage, although interviewees stated that access has improved.

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<sup>123</sup> According to the WHO these studies to evaluate the implementation of national medicines policies should be repeated every two years, but have been conducted just once in Brazil.

Although the importance and advantages of recording and monitoring the performance of implemented policies are well known, this is a neglected area in the basic pharmaceutical assistance field. Trying to circumvent this deficiency in monitoring, municipal and state secretaries gave new uses to the phenomenon of judicialisation of medicine supply and media news about shortage of medicines. Judicialisation is a clear sign that drug provision is not adequate to demand. Bearing this in mind, health secretaries use the decrease in the number of court cases demanding medicines as a proxy indicator of advances in the availability of medicines. Following the same line of reasoning, mass media news about the shortage of medicines is also used as an indirect indicator of access to medicine. If no news about the shortage of medicines is broadcast they assume that availability is satisfactory.

My interviewees suggested that deficiencies in the systematic evaluation of policies led managers to use their own mechanisms to estimate how the programme or policies implemented are performing, using available sources: media coverage of the lack of availability of medicines in SUS facilities, and number of lawsuits of citizens demanding drugs. These innovative indicators of performance, whose intended use is to infer the availability of medicines in SUS health services, are indirect and based on the absence of a specific event. The assessment consisted of scrutinising the news about scarcity of drugs, and the number of court cases demanding drugs. The next two quotes are examples of how the interviewees used media sources as a means to infer that access to medicines is satisfactory:

*Today, with the [Paraná] consortium<sup>124</sup> [of medicines] we do not have any more newspaper headlines, complaints on the radio, as we had ten years ago. It was very usual [to hear] people complaining about shortage of medicines for diabetes, hypertension, antibiotics, all medicines that are included in the list of basic Pharmaceutical Assistance (Interviewee 3; 1.3).*

This account illustrates how the absence of mass media news about failures in availability is interpreted as an indicator of good performance. Court cases brought by patients against the State in an attempt to obtain prescribed drugs are another proxy indicator of access.

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<sup>124</sup> The Paraná Consortium of Drugs is a successful experience in management of basic pharmaceutical assistance discussed in Chapter Four, section 4.5.

In the Brazilian pharmaceutical assistance context, lawsuits are a result of failure in provision.<sup>125</sup> Thus, the absence of, or reduction in the number of lawsuits to obtain drugs was used by interviewees as an indicator of improved access in the region. The next quote illustrates how the number of cases was used to assess the results of decentralisation:

*In Santa Catarina [state] the responsibility [for managing the provision of basic medicines] was distributed to each municipality and the fulfilment of this responsibility is monitored. This has given us spectacular results in terms of access. The level of judicialisation in relation to basic medicines is very low in the state (Interviewee 7; 9.1).*

The interviewee affirmed that decentralisation has brought ‘spectacular results’ and the evidence used to sustain this view was the decrease in the number of court cases, which it is called ‘level of judicialisation’. In the course of judicialisation, in addition to spending sufficient financial resources in a few cases to provide medicines for the entire population of the municipality, secretaries also had to buy medicines urgently or they could be arrested. Within this context, the decrease in court cases has important consequences for the municipality and can help to understand why the phenomenon is used as evidence of the progress made in availability of medicines, as noted by the interviewees.

It is noteworthy that the decrease in actions that require medications reported by the interviewee from Santa Catarina (quoted above), refers to basic medicines and does not include the high-cost medications. So what municipal managers are saying is that judicialisation decreased because the availability of basic medicines has improved. Nevertheless, at the state and federal levels the number of cases is still increasing, as evidenced by the figures provided by the analysis of the Office of the Attorney-General (Advocacia Geral da União, 2011). According to my interviewees, state secretariats’ efforts were focused on provision of high-cost medications and responses to this rising trend in court cases. This assertion is corroborated by the TCU report, which implies that the efforts to respond to judicialisation demands prevented the state level from satisfactorily performing their role of Pharmaceutical Assistance Coordinator. In my view, the context in which the state level is focused in providing high-cost medications, and dealing with lawsuits, can help to explain why they did not oppose implementation of the Popular Pharmacy Programme. This programme, as I will discuss, bypasses the state level and could be regarded as weakening state power. The argument about how this programme entered the policy agenda and prospered will be explored in Chapter Seven.

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<sup>125</sup> In some cases, medicines demanded in the court cases are not licensed to be marketed in the country or they are experimental drugs. So, in these cases it is not failure in provision.

## 6.5 Conclusion

This chapter summarises the main strengths of decentralised pharmaceutical assistance policy and outlines the barriers to improving access to medicines in primary care, according to the informants. Interviewees' accounts are contextualised within the policy framework and compared with available data about access.

Interviewees, in general, related decentralisation with the structuring of basic pharmaceutical assistance in municipalities, which resulted in increased access to basic medicines. However, besides this perceived positive impact of decentralisation, the provision of basic medicines has not yet reached universal coverage. Significant weaknesses and important barriers, as exposed by interviewees in this research, are preventing further development of the pharmaceutical assistance field.

Overall, this research has shown that interviewees associated decentralisation with a better level of access to basic medicines in certain regions of the country. Basic pharmaceutical assistance was organised in municipalities and states as a result of the decentralisation process, which distributed power and responsibilities. Decentralisation required the definition of roles and responsibilities for municipal, state and federal levels regarding the provision of medicines. To implement these new roles, municipalities had to create physical and administrative structures as well as planning activities related to the supply of medicines. These actions resulted, according to interviewees, in improvements in the availability of medicines.

However, as in primary care, important regional differences in public provision of basic medicines are observed. In some states and municipalities, important advances have been achieved, while in other regions the accounts showed that the situation is still very precarious. Regions with better access to medicines are the same ones that have better primary care coverage, which is expected, since pharmaceutical assistance and primary care are interdependent. The contrasting examples of Minas Gerais and Amazonas suggest that support provided by the state level to municipalities plays an important role in determining whether better results in basic pharmaceutical assistance will be achieved.

In general, all interviewees reported an improvement in access to medicines, but a more detailed analysis showed that major failures still occur. The possibilities presented by decentralisation of pharmaceutical assistance have not been translated into effective action, and the expected changes in terms of improvement in access to medicines have not materialised evenly across the country. Important barriers are delaying progress in the field. The problems are interrelated and consequently have mutual impacts. The main problems pointed out are: pharmaceutical care fragmentation; lack of integration between care and provision of medicines; insufficient financial resources; low management capability; and absence of tools and indicators to monitor programmes.

There is general agreement on the need to implement indicators and a monitoring system to evaluate pharmaceutical assistance. Currently there are no data to confirm the perception of the interviewees that access has improved over the last decade. In the absence of mechanisms and tools for monitoring access, health secretaries use the number of lawsuits to estimate if drug supply is satisfactory. A decrease in the number of court cases is associated with better provision of medicines. They attributed a new meaning to the judicialisation phenomenon.

As with the creation of SUS, the legal framework of pharmaceutical assistance is comprehensive and far-reaching, but it was not accompanied by the corresponding actions needed. In theory everything is provided, but in practice things are quite different. My findings indicate that the operational capacity of municipalities to manage basic pharmaceutical assistance is still inadequate to enable the universal coverage to basic medicines intended by SUS. There is still a large gap between the SUS legislation framework on pharmaceutical assistance and what is actually being delivered by states and municipalities. Achieving universal access to medicines will depend on the accomplishment of various steps, ranging from the manufacture of medicines to dispensing them to patients.

Within the accounts of my interviewees it was sometimes difficult to differentiate between statements pertaining to decentralised services being actually delivered by the municipalities from those not implemented but that were mandatory. When they contrasted what they should (or would like to) do with what was really happening, there was no clear line in their accounts separating intention from action. I could not explore if they mixed future goals with services already delivered intentionally in their speech, or whether it was just complicated for them to explain how policy-making happened. As Prainsack and Wahlberg argue, for policy-makers “a lot rides on being perceived as formulating rational and coherent policies”. In my work, how some interviewees handled the issue of monitoring the access and demands for medicines is coherent with the authors’

view of the effort of policy-makers. As I discussed, inconsistency in monitoring the access to medicines was pointed out as a significant failure in pharmaceutical assistance. In some accounts, however, my interviewees suggested that this was no longer a problem. They suggested that the software to support the national system of management created by the Ministry of Health, which included monitoring access, had solved the problem. Nevertheless, as I found out later, the implementation was limited to few localities. Thus, potentially, it could solve the problem if implemented, but this difference between intention and action was not clear in their accounts. What I could observe, is the unfortunate gap between what is provided in the legal framework and what has been delivered, a gap evidenced by the poor performance of basic pharmaceutical assistance as reported by the Court of Accounts of the Union (TCU).

## CHAPTER SEVEN

### THE POPULAR PHARMACY PROGRAMME: AN ALTERNATIVE WAY OF PROVIDING ACCESS TO MEDICINES

#### 7.1 Introduction

In 2003 Brazil went through an important political transition with the election of the first Workers' Party president. The left-wing candidate Lula was elected under the banner of fighting inequalities and poverty, opposing the neoliberal policies of former president Cardoso (Castro and Valladao De Carvalho, 2003). In his first term, however, to a certain extent Lula's administration remained connected to the neoliberal agenda. The Brazilian economist Fagnani (2011) argues that social policies under Lula (2003-2005) took place against the backdrop of tension between the "Minimum State" and the "Welfare State" paradigms. The first term (2003-2006), according to Fagnani, was marked by coexistence within the core of the federal government, of sectors defending universal rights and those advocating the "Minimum State". Eventually, however, the neoliberal camp lost strength, as a consequence of the global financial crisis from 2008 onwards.

This context of political transition helps in understanding why the Popular Pharmacy Programme (FP programme, hereafter), controlled by the Ministry of Health, was set up at the same time as decentralising the provision of medicines. In this initial period of Lula's administration it seems that to accommodate opposite paradigms, there was an attempt to improve universal access (decentralising the basic pharmaceutical assistance), but also to increase the coverage by the co-payment (with the FP programme). If we took this reasoning to the extreme, we could even identify a contradiction within the FP initiative: medicines are not totally free, but the prices charged are lower than those in private pharmacies because FP receives subsidies from the federal government. In sum, the programme is neither providing universal access in accordance to the "Welfare State" nor carries features of the typical "Minimum State". Although municipalities were already responsible for distributing basic medicines to the population, the Federal government wanted to link the new administration with a programme to improve the availability of medicines. The FP programme, which is aligned with other social policies created by the federal government at the beginning of its term, has become a trademark of Lula's government.

The FP Programme, nevertheless, encapsulates the limits of recentralisation because subnational actors had no voice in the policy designing which was created by the federal government (Aurea *et*

*al.*, 2010; Pinto, 2008). Moreover, although decentralised programmes to provide medicines under the auspices of the municipalities continued, within the FP programme the federal government took responsibility for the provision of essential drugs. The FP programme emerged within the context of decentralisation that has been in place as a pillar of SUS since the 1988 Constitution. The FP programme might thus be regarded as challenging the paradigm of decentralisation inherent in the Brazilian National Health Service (SUS) and indicates a new approach in the provision of medicines.

In this chapter I will discuss the implementation of the FP Programme, how it relates to the larger framework of pharmaceutical assistance, its impact on the provision of basic medicines, and its effects on the decentralisation process. The chapter is organised in six sections. The first gives an overview of the central features of the programme, how it was created, and its rationale. The subsequent section discusses the effects of FP implementation and how the programme contributed to solving existing issues in the provision of medicines. The criticism levelled at the programme and the consequences of decentralised provision are explored in the following section. How the strategy adopted to implement the FP helped to avoid the debate about recentralisation is discussed in the section that follows. The chapter closes with the main conclusions.

## **7.2 Why and how was the FP created? How does it work?**

The federal government's justification for recentralising control over the distribution of basic medicines relies on two main factors. The first was the frequent shortage of medicines in SUS pharmacies, which undermined the reliability of the public supply of medicines. The second factor was related to socioeconomic factors. In Brazil, a significant portion of the metropolitan population<sup>126</sup> had a private health plan but could not afford to buy medicines. This group was not among the primary users of SUS because their private health plans allowed them to use private clinics, hospitals and physicians. The Ministry of Health implemented the FP programme to improve access to and reduce costs of medicines for this group of non-SUS patients.

One could ask how a centralised programme, designed and controlled by the federal government such as the FP, emerged to take a central role in the provision of medicines, a task that was among those of the decentralised system. The interview data that I collected indicate that it was the

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<sup>126</sup> This group includes citizens with household budget ranging from 4 to 10 minimum wages. This group includes about 14% of Brazilian families (IBGE-Brazilian Institute of Geography and Statistics, 2011)

President of the Republic himself who decided to create the programme. In fact, the political power of President Lula was decisive in setting up the FP. In tune with the President's view, the Minister of Health and the officials involved with pharmaceutical assistance<sup>127</sup> were also committed to implementing the programme. This commitment and influence were important if we consider the FP's innovative strategy to improve the availability of medicines. The FP strategy is based on two controversial features: First, users' co-payment, and second, centralised management. Before we discuss these features in more detail, let me give a more systematic overview of the programme.

### 7.2.1 Features of the programme

The FP programme was established in 2004 by the federal government to dispense medicine to treat prevalent diseases in the country (Ministerio da Saude, 2005b) Patients had to pay 10% of the costs out of pockets, and the government subsidised up to 90%. This is the only Brazilian health programme that involves users' co-payment. The rationales presented by the Ministry of Health to introduce co-payment were the need to expand access to medicines considering that a significant portion of the population used private health services and bought medicines on the private market. The Ministry of Health's justification, in the bill proposing the co-payment, was that it could reduce the impact of drug expenditures in the household budget and contribute to the expansion of the access to the treatments. The federal executive argued that these actions would benefit patients that otherwise would abandon treatments because they could not afford buying medicines. This adherence to the treatments due to subsidised drug prices provided by the FP, in turn, would result in less cost in health treatments and consequently saves on public resources.<sup>128</sup>

The FP has a public and a private arm. The public arm was implemented in 2004, and has public pharmacy facilities (called 'public owned' pharmacies or simply 'owned')<sup>129</sup> set up and managed by Oswaldo Cruz Foundation (FIOCRUZ – *Fundação Oswaldo Cruz*) and the Ministry of Health<sup>130</sup>

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<sup>127</sup> Pharmaceutical assistance is a broad term created in Brazil to designate health care activities involving medicines. According to Marin *et al.*(2003), the definition of pharmaceutical assistance involves comprehensive, multiprofessional and intersectoral activities connected to the management of services related to medicines in its various dimensions, with emphasis on the relationship with the patient, the community and health promotion. In this sense, the public delivery of medicines by SUS and its management is also part of pharmaceutical assistance.

<sup>128</sup> These arguments are part of the justification of the bill 5235/2005, which introduced the co-payment, proposed by the Ministry of Health to the Congress. This document is available at: [http://www.camara.gov.br/proposicoesWeb/prop\\_mostrarintegra?codteor=306211&filename=Tramitacao-PL+5235/2005](http://www.camara.gov.br/proposicoesWeb/prop_mostrarintegra?codteor=306211&filename=Tramitacao-PL+5235/2005) [last accessed on 25/07/2013]

<sup>129</sup> In this work I use 'owned' network and 'owned' pharmacies (meaning owned by the federal government) to designate those pharmacies built in municipalities exclusively for the FP programme. Those pharmacies are managed by FIOCRUZ.

<sup>130</sup> FIOCRUZ- Oswaldo Cruz Foundation is a federal foundation that reports to the Ministry of Health.

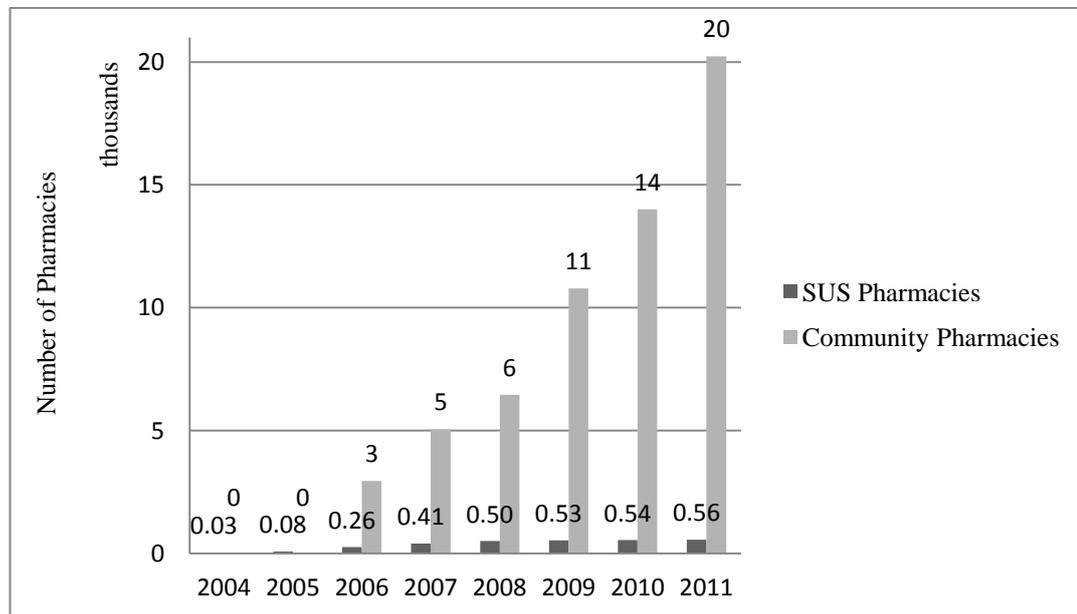
in partnership with states and municipalities. The private arm, which began in 2006, incorporated accredited community (private) pharmacies. At present, FP has public and private arms working simultaneously. Alongside the implementation of the programme important changes were introduced. The positive results in terms of access and rapid expansion are among the factors that have driven those changes. In order to facilitate the understanding of the modifications introduced I will separate the process of the implementation of the FP into three stages, as explained below.

### **7.2.2 The implementation stages**

*The first stage* commenced in 2004 with public pharmacies (the ‘owned’ network) managed by the Ministry of Health/FIOCRUZ. The primary goal of the FP was to make medicines available, at affordable prices, to private health plan users. These public pharmacies were installed in central areas of state capitals and municipalities with at least 100,000 inhabitants. These facilities were exclusively built or refurbished to comply with standards set by FIOCRUZ. Currently, 557 pharmacies participate in the ‘owned’ network, which covers 441 municipalities around the country. The partnership with municipal health secretariats was restricted to the decision of where the pharmacy should be installed within the territory. The management of all other activities, such as the purchase of medicines, funding, logistics, distribution, and remuneration of staff, is centralised and controlled at the federal level. Unlike SUS basic pharmacies, these new units received exclusive federal financial support for their construction and furnishing. Additionally, each ‘owned’ FP facility is entitled to a monthly sum to pay staff and maintenance. These financial aspects mark important differences between the FP public arm and SUS basic pharmacies. In short, the federal government financed the construction and maintenance of a network of standardised pharmacies to be used exclusively by the centralised programme.

*The second stage* began in 2006 when the programme was extended to the community pharmacies network. This expansion was called *Aqui Tem Farmácia Popular* (‘there is a popular pharmacy here’). At this stage existing community pharmacies entered into a contract with the Ministry of Health. Contract clauses are set down in the legislation and the maximum value paid for each drug is set by the federal government. This second stage of the programme was implemented rapidly, and participating community pharmacies grew from 2,955 in 2006 to 20,225 in 2011. At present, 3,359 municipalities (out of 5,565) have community pharmacies that are part of the FP. These figures contrast with just 441 municipalities that have FP public (‘owned’) pharmacies. Since 2009, the Ministry of Health seems to have lost interest in the public arm of the programme, considering

that only 27 new ‘owned’ pharmacies have been introduced in three years, whereas accredited community pharmacies<sup>131</sup> almost doubled in the same period, as shown in figure 7.1.



**Figure 7.1 – Growth in the number of pharmacies in the Popular Pharmacy Programme in Brazil in total**

Source: Produced by the author according to data available from Sala de situação Ministerio da Saúde (Situation Room of the Ministry of Health) available at <http://189.28.128.178/sage/>

Figure 7.1 compares the number of ‘owned’ and accredited pharmacies, from the beginning of the FP programme in 2004 until 2011. The figure shows that from 2006 to 2011 the percentage change observed in pharmacy facilities corresponds to 115% in the public arm (represented by the ‘owned’ pharmacies) against 584% observed in community pharmacies, which are the private arm of the programme. The growth of the private arm overtook the programme and now citizens usually associate the FP programme with the private sector. This means that the community pharmacies, i.e. the private sector, are the place where SUS and non-SUS patients go to receive medicines.

Grounded in the accounts of my interviewees, in my opinion, the slow pace of implementation in stage one, evidenced by the low number of ‘owned’ pharmacies installed in the first and second year, motivated the partnership with the private sector that was to make the programme take off. In

<sup>131</sup> In my work I am using private pharmacies and community pharmacies as synonyms. In fact, in Brazil the term private pharmacy is more used. Accredited pharmacies or participating pharmacies refer to pharmacies that entered into a contract with the Ministry of Health.

fact, the resources devoted to the programme grew from about £8 million, in 2006, to £200 million in 2009 (Tribunal de Contas da Uniao, 2010)<sup>132</sup>.

In 2011, the government implemented the *third stage* with the initiative *Saude Não Tem Preço*<sup>133</sup>. This stage started the distribution, free of charge, of drugs to treat diabetes and hypertension in ‘owned’ and community pharmacies. In addition to these free medicines<sup>134</sup>, FP is still dispensing drugs in the co-payment scheme for the treatment of cholesterol, osteoporosis, Parkinson's disease, glaucoma, rhinitis and dyslipidemia, as well as providing contraceptives and geriatric diapers. Currently, the FP programme offers 25 items, of which 14 are distributed free of charge and the other nine being sold with a discount of up to 90%.

### 7.2.3 The rapid expansion of the FP programme

The partnership with the private sector was a turning point in the programme’s implementation. The capillarity of the community pharmacy network allowed non-SUS patients access to medicines, for whom the programme was originally designed, but also resulted in access for SUS patients.

An important aspect that helps us to understand the accelerated development of the FP was the failure in the distribution of medicines by SUS pharmacies. The availability of basic medicines in SUS pharmacies did not meet the population’s needs. In other words, SUS has historically been unable to provide sufficient medicines. This lack of consistency caused a shortfall in access, which in turn gave the FP room to develop. In the quote that follows, a Ministry of Health official explains that SUS did not manage to distribute medicines consistently, whereas the FP did:

*Taking into consideration everything I already told you about Basic Pharmaceutical Assistance, and that SUS is still in a stage of consolidation, we have to admit that we could not organise our Farmácia Basica [SUS] to ensure the same level of access that the FP achieved (Interview 19; 8.2).*

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<sup>132</sup> Original figures in Brazilian Reais R\$34724 million (2006) and R\$562.42 million (2009), respectively. I used a £/R\$ 4.18 and 2.83 conversion rate, respectively. Rates obtained at [www.xe.com](http://www.xe.com) [accessed on 18/04/2011]

<sup>133</sup> ‘Health is Priceless’. The expression alludes to the introduction of free medicine provision.

<sup>134</sup> Since 2012, FP has also distributed medicines to treat asthma, free of charge.

To this interviewee, inefficiency in the public provision of medicines is a consequence of the incomplete implementation of SUS, which led to a lack of management capability. The interviewee compares the access offered by the *Farmácia Básica*<sup>135</sup> and the FP and concludes that SUS did not make medicines available to patients in the necessary quantity or at the right time, whereas the FP did. However, it is worth noting that this opinion comes from a person who represents the federal level and therefore was likely to take the view that the federal-run FP solved the access problem that the decentralised SUS could not address successfully.

Medicine to control diabetes and hypertension both play an essential role in the nation's health and are a good example to illustrate the FP's rapid expansion and importance. In 2011, when distribution free of charge started, from January to November, 6.973 million patients with diabetes and hypertension received their prescribed medicines from the FP (Pereira, 2011). In the next quote, the same interviewee continues to build up the justification for FP growth based on the inefficiency of the SUS in providing these drugs:

*SUS could not give us the answer [to the access problem] and ensure qualified access to medicines for hypertension and diabetes. If SUS had given the answer, the FP would not show this rapid expansion in the number of patients assisted in a few months (Interview 19; 10.1).*

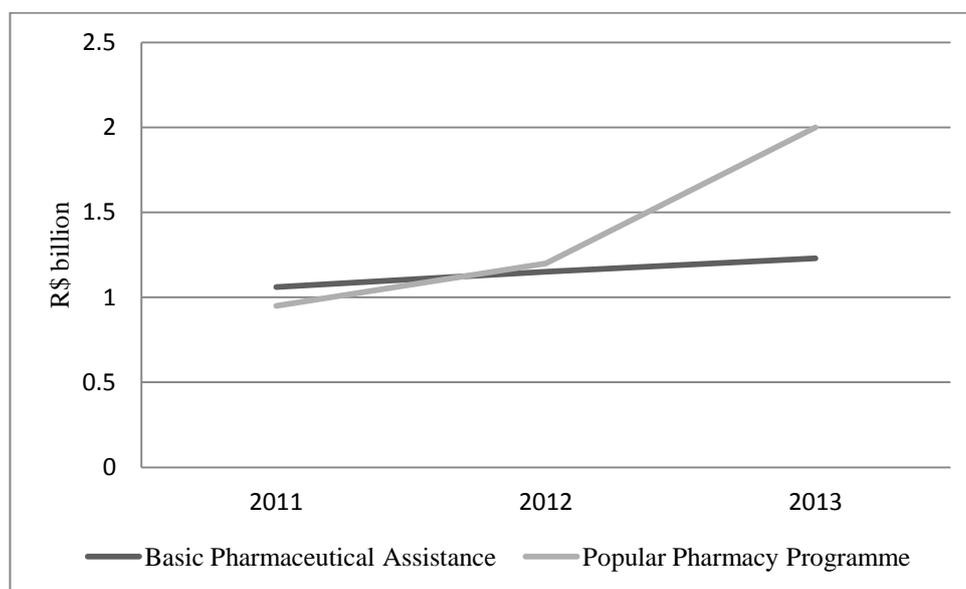
According to the interviewee, if SUS had distributed these drugs adequately, then the FP would not have grown as fast as it did. The rise in number of patients assisted by the FP is associated with the shortage experienced at the SUS. This account, however, should again be viewed with caution, considering that it comes from a Ministry of Health official, who would not be unbiased in justifying the need for the implementation of the FP. Moreover, another factor not considered by the interviewee, but one which influences this equation, is the high number of community pharmacies in the country. Certainly, the size of the network affects the number of patients reached. Hence, just the availability of drugs could not account for the rapid expansion of the programme. Accreditation of community pharmacies grew and spread throughout the country without any kind of federal guideline regarding geographical location until reaching about 20,000 pharmacies representing 24%<sup>136</sup> of all private pharmacies in the country in 2010.

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<sup>135</sup> *Farmácia Básica*, as discussed in previous chapters, is the SUS decentralised programme for provision of basic medicines.

<sup>136</sup> According to the audit committee of the CFF, the Federal Chartered Board of Pharmacy, there were 82,204 community pharmacies in 2010.

Another factor that helps to explain the development of the FP is related to the financial funds invested. The budget allocated to SUS basic pharmaceutical assistance compared to the FP programme budget shows that from 2011, when distribution of free diabetes and hypertension medicines started, FP has received resources comparable to those allocated to the entire SUS basic pharmaceutical assistance. In 2013, the budget was much higher for FP than for the whole of SUS's basic pharmaceutical assistance, as shown in Figure 7.2 below. It is worth noting that FP distributes only 25 items to 3,353 out of 5,565 municipalities, while SUS basic pharmaceutical assistance programme is responsible for providing about 120 items to all municipalities in the country.



**Figure 7.2 – Budget allocated to SUS Basic Pharmaceutical Assistance compared to Popular Pharmacy Programme**

Source: author, according to data presented in the Farmácia Popular-Public Hearing at Câmara dos Deputados/Comissão de Segurança Social e Família, Brasília in October, 2012

The figure illustrates the trend described both by my interviewees and by Ministry of Health efforts and resources allocated. The FP was prioritised and received major investments, allowing its rapid expansion throughout the country. From 2011 to 2013, the SUS basic pharmaceutical assistance budget grew only 17% compared with an increase of 110% in the FP budget in the same period, evidencing federal government commitment to the programme. These figures strongly suggest that the centralised FP programme was the strategy chosen by the federal level to improve access to basic medicines. Moreover, judging by the large financial investment put in the programme it is reasonable to assume that the federal government was expecting positive results, and these did in fact occur soon afterwards. These positive results in terms of patients' usage and medicines

delivered justify the increase in investments, which in turn helped to further boost FP implementation.

In the section that follows I will explore the contribution of the FP programme to the solution of SUS' problems in the provision of basic medicines.

### **7.3 How did the FP approach persistent problems and barriers involving public pharmaceutical assistance?**

My analysis so far begs the question why this programme has been successfully implemented while public provision of medicines in SUS facilities still remains inadequate. I consider that the barriers to the advancement of SUS basic pharmaceutical assistance discussed in Chapter Six, section 6.4, are an important part of the explanation. Those barriers are related, mostly, to insufficient funds, low management capability, regional differences, and lack of planning and monitoring. The other component of this explanation is related to the federative arrangement, and the subnational autonomy<sup>137</sup> which directly affects SUS management, as discussed in Chapter Five. Due to the autonomy given to states and municipalities by the Brazilian Constitution, the implementation of policies and programmes is preceded by negotiations and agreements between the three levels of the federation: union, states and municipalities. In the interviews, this process was described by Ministry of Health officials as being laborious and time consuming. In my view, these requirements of negotiation and agreement have helped encourage the federal authorities to search for an alternative to such a process.

Another interesting question in this context is why the federal government decided to focus its efforts on the private arm of the programme, instead of the public arm. I found indications in the interviewees' accounts that the federal level saw in its private partners an opportunity to achieve the distribution of basic drugs efficiently and at the same time to avoid the tiers of laborious negotiation with SUS.

Some of the obstacles to the full development of SUS basic pharmaceutical assistance, mainly regarding access to essential medicines, are successfully overcome with the FP. The main barriers

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<sup>137</sup> Autonomy of state and municipalities include a degree of administrative, financial and political power for the exercise of the local or regional government and administration. State's legislative power is limited to regional issues whereas municipalities can only legislate on local issues.

pointed out by interviewees and corroborated by literature relate to insufficient financial resources, infrastructure, and human resources. Throughout the implementation of the FP the federal government has been working on each of these obstacles. The partnership with the private sector was the turning point in the implementation of the FP. The community pharmacies network contracted by the FP provided at a stroke the infrastructure, the human resources, and the management capabilities necessary. According to the Ministry of Health, to have built and furnished the 20,000 FP accredited pharmacies (which were already up and running) would have required investment of about R\$ 1.8 billion (Ministério da Saúde, 2012).

Another only partially solved problem was the lack of monitoring of indicators of access to medicine, an issue pointed out by interviewees as an obstacle to the development of pharmaceutical assistance. Due to the very nature of the commercial relations in the private sector and the contract signed with the Ministry of Health, FP facilities keep records of the number of patients assisted, and the medication and dose dispensed. They need to keep track of this information in order to receive payment for the service. Contrasting with SUS basic pharmaceutical assistance, FP is the only drug provision programme that keeps all these records. Currently, these records represent the only source of systematic data on access to essential medicines available in Brazil.

Further to government savings due to the infrastructure brought in by the private partner, federal government officials also noted management benefits arising from the FP. To rebut criticism, these officials often mention some features, inherent to the private sector, which make the FP programme advantageous when compared to SUS pharmaceutical assistance. Community pharmacies have convenient opening times, an adequate number of trained employees, infrastructure and management capability; they keep a comprehensive stock of medicines, and use a wholesale service to fill prescriptions promptly. According to Ministry of Health officials, all these elements were incorporated into the federal programme without any additional cost. The capillarity of the private network that is spread in almost all regions of the country was another characteristic that brought important benefits to the programme. In the next quote a state health secretary talks about the advantages of the territorial coverage of the private pharmacy network. In this account the infrastructure provided by the private partner, the presence of a pharmacist in each facility, and the logistics of supply are all counted as advantageous when compared to SUS:

*The initiative reaches small and large municipalities, from capital cities to small municipalities and districts. The programme made the access easy and this is an improvement because, as I already said, [infra]structure is the problem. It is complicated for municipalities to have pharmacies in each of their healthcare facilities, and even more*

*complicated is to have a pharmacist in each of these pharmacies to dispense the drugs. The distribution of these drugs is much easier in the network of accredited pharmacies (...). The [community pharmacies] network already has all the structure of distribution and the logistics (Interview 2; 12.1).*

This account summarises the main features of community pharmacies that made FP advantageous when compared to SUS basic pharmaceutical assistance. Commercial networks are more efficient and are presented as a good way to improve access. The interviewee found in the private partner the solutions to persistent problems faced by SUS in attempts to improve the provision of medicines.

Another likely explanation for this preference relates to the rapid response of private partners to federal government demands. In the quote that follows, this Ministry of Health official reviews characteristics of the private sector that make it advantageous compared to SUS. According to the interviewee, availability of medicines has been solved by the FP programme. The success of the initiative, however, unveiled a new challenge, as the respondent explains:

*The problem now is no longer the availability of drugs, the problem now is to provide qualified access and pharmaceutical assistance. We need to know if hypertensive patients and diabetics who are receiving medications in the FP are being monitored and having the necessary health care. The community pharmacy does not monitor treatment. In the case of the SUS basic pharmacy, only a few municipalities, who are more structured, offer this service. We'll have to make a decision here, and qualify such access in private pharmacies. And I think it's easier to qualify access in private pharmacies. Yes it is easier. If the government asks [the private sector] to accredit the pharmacy [to the FP programme] this pharmaceutical service must be done, so the private sector will do it. At SUS, we'll enter a series of negotiations and agreements which we could not solve in one, two or three months. This will take a lot longer than that (Interview 19; 8.4).*

The interest in and satisfaction with the private sector's performance are apparent in the quote above. The interviewee remarks that as drug availability had already been solved the programme's next step should be the improvement of pharmaceutical care.<sup>138</sup> According to him, this step would also be easily achieved if the government invested in the private partner instead of in the SUS.

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<sup>138</sup> According to Hepler and Strand (1990:539) the definition of pharmaceutical care is "the responsible provision of drug therapy for the purpose of achieving definite outcomes which improve a patient's quality of life."

Pharmaceutical care entails having a pharmacist to provide information and advice to help the patients to use medicines safely and efficiently. The justification for using a community network to improve pharmaceutical care instead of SUS is that in the public service there is the requirement of successive negotiations in various forums before the changes proposed can be implemented. Thus this process within the SUS is bound to take longer than in the private sector. Considering the potential political dividends from the FP and the restricted time within a presidential term, I would argue that the government took the faster alternative.

In line with this reasoning, I would add that within SUS forums any new proposal has to be approved by consensus, and the subnational actors can propose modifications and amendments that could result in changes to the policy proposed. In contrast, the private partners have a contract and consequently they will do what the federal government asks them to do in order to be paid. In this way a standard policy that fits within the federal government's agenda can be implemented throughout the country.

In short, use of the existing infrastructure and its agile response to government's demands provided by the private partners has been instrumental in shaping the programme. Both Ministry of Health officials and health secretaries praised the positive results of the programme in terms of availability of medicines. Remarkably, the health secretaries have barely reacted to the fact that a programme to distribute basic medicines controlled by the federal government is advancing and competing for SUS patients. I would have expected a more critical view, considering the top-down policy-making that is characteristic of the FP programme, and the limited participation of the health secretariats in the decision-making. In my view, based on my interviewees' accounts, a likely explanation is that the municipal and state health regarded the FP as a solution to some of their problems. Secretariats are under constant pressure to deliver medicines and more than often do not have these drugs in stock. The FP brought concrete benefits to local government, which weakened opposition to the programme.

From the private sector's perspective, on top of the economic advantages related to the larger clientele brought to community pharmacies, the partnership with the federal government is also valued because it is similar to other well established models that provide medicines around the world. The president of ABRAFARMA, the Brazilian Association of Pharmacies Network, which represents 57,000 community (private) pharmacies, argues that the partnership with the federal government is the future of pharmaceutical assistance in Brazil (Longaresi, 2012) As he argues, "It is the way it works all around the world, sale of subsidised medicines, with refund from the

government.” In fact, FP distribution of drugs has similarities with other countries, such as NHS provision of medicines through community pharmacies in the UK.

Having discussed the development of the FP programme and how it compares with SUS provision of medicines, in the next section I will consider what has changed for the users.

#### **7.4 Citizens’ uptake and the replacement of SUS pharmacies in the provision of basic medicines**

Since 2006, the FP programme has assisted 19 million people. The community pharmacies network performed 34 million dispensations in 2011 (Ministério da Saúde, 2012). Of the 17.5 million people served by the programme from 2011 to January 2013, 13.6 million received free medication for hypertension and diabetes<sup>139</sup>. During this period, the number of diabetic and hypertensive patients enrolled in the programme grew 457%: from 853,000 in January 2011 to 4.7 million in January 2013. Considering the increasing number of patients whose medicines are dispensed via the FP, it is reasonable to infer that SUS patients are migrating to the FP. In fact, Santos-Pinto *et al.* (2011) showed that 46% of FP users came from SUS in 2009, arguing that the frequent shortage of medicines in SUS pharmacies explains this migration of SUS patients to the FP.

In addition to historical failures in public provision of medicines, another three interrelated circumstances could help to understand this migration. Firstly, FP combines characteristics such as the location, convenient opening hours, and continuous availability of drugs that seem to attract and satisfy patients. The advantages of FP location compared to SUS facilities and the implications for users’ transport expenses are evidenced by the comments of a municipal health secretary, as follows:

*He [sic; the patient] searches [for medicines] in the Popular Pharmacy where they are highly subsidised and therefore more accessible. Often he would spend more money on transportation to get to a basic health care unit than he spends going to the Popular Pharmacy, which is strategically located (Interview 1; 3.3).*

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<sup>139</sup> The number of patients that had drugs dispensed by the FP and the proportion that had received drugs free of charge is provided in the Federal Government website. Available at: <http://www.brasil.gov.br/noticias/arquivos/2013/02/15/gratuidade-de-medicamentos-beneficia-14-milhoes-de-pessoas/print> [last accessed in 25/07/2013]

The respondent has shown that the location of the FP facilities plays an important role in attracting patients. The FP is “strategically located” because there are pharmacies in places where many people circulate, often on their way to work every day, usually in the high street or near train, underground and bus stations, for example. Moreover, the comparison between SUS facilities and community pharmacies highlights the very divergent nature of the public and the private sector. The former is focused on (public) health whereas the latter is commercially driven. Commercial activity of the private network causes the operation to be adapted to the consumers’ needs, resulting in convenient opening hours, as illustrated in the next quote:

*Here the patient has two options: either he [sic] goes to SUS and receives the medication free of charge or if he is hypertensive or diabetic he can seek the popular pharmacy network and also get free access to these drugs. This helps because the popular pharmacy often works until 19h, and [its location] also [helps to] prevent extra transportation expenses. If you have a prescription you will have access to the medication at the Popular Pharmacy. I think it was a big advance and this initiative should advance even more (Interview 2, 6.3).*

According to the interviewee, the opening hours and location of private pharmacies were important in implementing the programme. This assessment is supported by Santos-Pinto *et al.* (2011), who noted the better location of the FP compared with the basic health units and the longer waiting time for obtaining medicines in SUS, which contrast with consistent availability of medicines in FP. These factors are likely to influence patients’ choice.

The second aspect that helps to explain patients’ migration from SUS to the FP pharmacies is related to preferences and actions of the municipalities. Some municipal health secretaries seem to encourage SUS patients to use the FP facilities. These health secretaries see the FP as a reliable source of medicines and they prefer, and even advise, patients to seek medicines at the FP. As a consequence of the distribution of medicines by the FP, those municipalities started reducing the amount of medicines purchased so they rely on the FP when their stocks decrease or finish. This is well illustrated in the next quote by a municipal health secretary:

*So when the FP was implemented it took over acquisition and distribution of drugs that were part of our regular purchase. FP is a very successful experience, because it works continuously and medicine shortage is very rare. Indeed for me it was a relief because I reduced the purchase of these items in the municipality. Since FP is freely accessible to any citizen I do not need to have much stock [of medicines] in the warehouse. I don’t need to be concerned in acquiring drugs for hypertension and diabetes. That makes a big*

*difference for me because I do not need to take the resources of the municipal pharmaceutical assistance and use them in drugs that the FP distributes, I don't have to do that. So it decreases my expenses (Interview 11; 7.2).*

In practice, this municipal health secretary has integrated the FP distribution of medicines into the municipal provision of medicines. In fact, the municipal health secretary in the extract above makes it clear that distribution of medicines by the FP was a relief for the municipality, which has come to rely on the programme to provide diabetes and hypertension medicines for SUS patients. Trust in the programme has led the municipality to decrease its stocks of drugs and to refer these patients to the FP pharmacies. By doing so, municipalities are, in practice, devolving control of the provision of medicines. It is important to highlight that although the FP changed the way medicines are accessed, the legal framework remains the same. This means that municipalities continue to receive financial funds and have responsibilities to provide basic medicines. However, it is reasonable to suppose that municipal provision of basic medicines will lose importance as a result of relying on the FP to provide medicines to the SUS patients and the consequent migration of these patients. In my view, the fact that municipal health secretaries are referring patients to FP has contributed to the increasing importance of the programme as well as dependence on the private sector.

The third factor that helps to understand patients' motivations for migration is related to the perception that the community pharmacies provide better quality and using them is not associated with being a low-income user. Lima (2009) studied the paths taken by patients seeking medicines in SUS facilities in Manaus. The patients interviewed by this researcher reported indifference from civil servants and long waiting times to receive information or to obtain the prescribed medicine. The journey is long, circuitous and humiliating, according to patients' accounts. They feel humiliated because, although they are entitled to receive the drug, they are forced to long journeys in the search of these drugs, which are not available in SUS health services. Lima (2009) argues that interviewees associate their difficulties in obtaining medicines with the fact that they are poor. That work revealed the patients' perception that only poor people use SUS and, because they cannot afford to pay for a health plan or the prescribed medicines, they have no other choice but to be submitted to this demeaning situation. Taking into account the users' perception of SUS services mainly being used by low-income clients, it is reasonable to infer that FP community pharmacies will attract these SUS users, who would prefer not to be seen as poor or low-income patients. President Lula's speech illustrates very well the perception that using SUS is linked to being poor, and also helps to understand why FP attracts SUS patients. In the first years of the FP programme President Lula stated:

*[If a] man or woman goes to a pharmacy accredited to the Popular Pharmacy [programme] nobody will ask [them] how much they earn for salary; no one will ask their social origin. If it is a Popular Pharmacy, they will [simply] buy the medicine for hypertension and diabetes there.<sup>140</sup>*

In his speech President Lula associates the Popular Pharmacy with a place where both SUS and non-SUS patients go to buy or receive medicines without being differentiated according to their purchase power or social strata. Previous to FP programme, community pharmacies were associated with those that had money to pay for medicines out-of-pocket, whereas SUS pharmacies distributed medicines to those that could not afford buying them. FP community pharmacies deliver medication to high, middle and low-income people without class distinction. In FP community pharmacies patients are not identified as being a SUS patient (and, consequently, as being “poor”); all users receive the same attention.

As discussed in this section, the high uptake by users, rapid expansion and migration of SUS patients to the FP have been fundamental for the success of the initiative. Moreover, as the implementation progressed the programme has changed its objectives. SUS patients, who were not even among the objectives during the first stage, have become a priority. From 2011 the Federal Government established that accreditation of new pharmacies to the FP would occur primarily in municipalities that had people who were living in poverty<sup>141</sup>. Those municipalities were mapped by the last census in 2010. Therefore, the provision of free medicines throughout the FP is part of a major goal of reducing poverty in these areas. While in this section I discussed how the FP solved some important issues in the provision of medicines and how this has impacted the decentralised system, in the next section I will explore, in more detail, the how the federal government has responded to open criticism of it.

## **7.5 Openly formulated criticism**

In the interviews I conducted, the FP was the subject that motivated respondents to talk the most. The programme is controversial; nevertheless, rather than there being two different camps whose

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<sup>140</sup> This is a fragment of President Lula speech about the Popular Pharmacy programme that is available in Portuguese in a webpage of a Workers’ Party representative. I translated it into English. Available at: <http://vaccarezza.com.br/lula-estimula-adesao-a-farmacia-popular/> [last accessed 22/08/2013].

<sup>141</sup> This initiative is published in the Ministry of Health website. Available at : [http://portal.saude.gov.br/portal/saude/visualizar\\_texto.cfm?idtxt=40501&janela=1](http://portal.saude.gov.br/portal/saude/visualizar_texto.cfm?idtxt=40501&janela=1)

members mentioned exclusively the alleged benefits and problems of the programme respectively, most of my interviewees pointed out positive and negative aspects of the programme in their accounts. An exception was only an official at the Ministry of Health, who was entirely in favour of the programme. Most interviewees were on the fence: while recognising that access to medicines had improved as a result of the FP, they also indicated that the programme had led basic pharmaceutical assistance away from decentralisation. Since the publication of the National Medicines Policy in 1998, all initiatives were aimed at decentralising the management of provision of basic medicines, but with the FP, in practice, control returned to the federal government. In a relatively short period of time the programme achieved significant results in terms of patients assisted and medicines dispensed, and these results contributed to legitimising the initiative. The improvement in access undermined health secretaries' opposition to the programme, even if there were criticisms of the programme. The high level of patient satisfaction with the FP adds even greater complexity to the situation. Even so, there are some points that were openly criticised by health secretaries, the co-payment scheme and the lack of integration between FP and SUS.

### 7.5.1 Co-payment

The main criticism at the launch of the programme in 2004 was targeted at the co-payment strategy, which was a 'first' in the history of medicine provision in Brazil. Universal health coverage, free of direct costs to users, is a fundamental SUS principle, which was undermined with the implementation of co-payment for medicines. The FP was viewed with reservations by the national boards CONASS, CONASEMS, CNS<sup>142</sup> and, also, by scholars in the field of public health. Criticism was based on the premise of gratuity on medicines provided by SUS in contrast to the co-payment applied by FP. The concern was that the co-payment of medicines could pave the way to other cost-sharing practices for services such as diagnostic tests, minor surgery and medical appointments. Those who opposed the programme advocated that co-payment should be prevented; otherwise the strategy would become common and would undermine the SUS pillars of universality and gratuity of access. The opposition, however, was weakened by the reasoning that the FP would benefit a significant portion of the population, as shown in the quote that follows:

*CONASEMS objected when the popular pharmacy was launched. Primarily, because we understand that there couldn't be co-payment of any kind in SUS. However, after numerous meetings and resistances from municipal secretaries, we just gave up. Why? Because we saw that a big slice of the population could benefit and that the mayors were also interested in offering something to help the population that does not use SUS. They could have some kind of subsidy to purchase medicines (Interview 14; 9.1).*

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<sup>142</sup> The creation, role and composition of these boards are discussed in detail in Chapter 1.

CONASEMS, which brings together municipal health secretaries, was against users' co-payment but withdrew their opposition because the population in the municipality could benefit from subsidised medicines. The interest shown by mayors in having subsidised medicines distributed to non-SUS patients also contributed to CONASEMS' decision. Municipal and state health secretaries were both against users' co-payment. Yet in 2004, when the FP was launched, CONASS sent an official letter to the Minister of Health (CONASS, 2004), expressing concern that the programme was unconstitutional because it introduced monetary contributions from the citizen in order to obtain medications that should be provided free of charge by SUS (Carvalho, 2004).

It was only after seven years of using user co-payment exclusively, that the federal government changed the FP to include the distribution, free of charge, of diabetes and hypertension drugs. This change from co-payment to gratuity was considered a shift in the right direction as explained by this state health secretary in the next quote:

*It was a conflicting idea, contradictory within SUS, this proposal from President Lula to set up the popular pharmacy. Until today it is still arguable. The Popular Pharmacy, however, allowed the population to have access to drugs at a very low cost. (...)Initially there might be this contradiction with the co-payment in private pharmacies, but I think this contradiction no longer exists because within this programme the community pharmacies network today distributes, free of charge, medicines for diabetes and hypertension (Interview 5; 7.2).*

As explained by this interviewee, the FP has improved access, but the strategy chosen contradicted the SUS fundamental principle of being free of charge. The programme could not be entirely embraced, so free of charge distribution was adopted to solve this problem. This became apparent when this Ministry of Health official was asked why gratuity was introduced in the FP:

*We have to understand the FP, the two arms [public and private], as a complementary mechanism of SUS. (...) Diabetes and hypertension are free because these are the main chronic diseases responsible for the major causes of mortality. (...) So gratuity comes to complement SUS. It comes to strengthen access. Gratuity fulfils another strategic goal which is to "get the goat out of the room"<sup>143</sup>. The goat was the co-payment. It was the ministry [of health] implementing a programme that charged for medicines. (...) With the gratuity we no longer have "a goat in the room". There were no more allegations that we*

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<sup>143</sup> It is a popular saying that means removing an obvious obstacle.

*charge for drugs, that we were privatising SUS, or anything along those lines (Interview 13; 10.2).*

The introduction of the gratuity was strategically executed to remove an obstacle to the acceptance of the programme. It could be argued that making the distribution of medicines free for treatment of just two diseases would not be sufficient to reverse the co-payment criticism, considering that many other medicines are still being charged for. Actually, the impact of this measure can be assessed by taking into consideration the percentage of diabetes and hypertension drugs among the total drugs dispensed. According to the Pharmaceutical Assistance Director, currently 76%<sup>144</sup> of all medicines dispensed via the FP are free of charge, i.e. 76% are medicines to treat diabetes and hypertension. Taking these figures into consideration helps to understand why making just these two medicines free was enough to neutralise criticisms. In short, users' co-payment was reduced to just a quarter of all medicines dispensed by the programme.

### **7.5.2 Dispensation of medicines is not integrated within pharmaceutical assistance and health care**

An additional aspect of the FP pointed out by state and municipal health secretaries as challenging was the integration of the distribution of medicines within SUS primary health care services. As with the other aspects discussed previously, accounts of the FP were ambiguous. My interviewees agreed that the programme was effective in providing access but at the same time the FP undermined the development of comprehensive SUS pharmaceutical assistance. This is because the pharmacies participating in the programme do not have any kind of communication or interaction with the SUS. A basic requirement for pharmaceutical assistance is that the pharmacist and the physician or nurse should be able to communicate and share data and information about a patient's health and treatment. As FP implementation advanced, more patients went to community pharmacies to get their medication. The main service provided by these private community pharmacies is dispensing drugs, as they are primarily commercial establishments that sell drugs and have no connection with the SUS. Moreover, even the dispensing service at community pharmacies may be considered inadequate because trained pharmacists are frequently absent from the premises (de Castro and Correr, 2007) Thus, lack of integration between drug distribution and pharmaceutical care has led to dissatisfaction with the FP among interviewees, although they could not ignore the advances in access. The following extract illustrates this contradiction between access and care:

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<sup>144</sup> Data presented in Farmacia Popular-Public Hearing at Camara dos Deputados/Comissão de Seguridade Social e Família on 16th October 2012

*Now, what was the assessment that we did on the occasion of the launch of the programme and I believe that somehow is still valid? We make a great effort to not see drugs as something separate from care. For us, for me as a health secretary, the medication has to be linked to care and to assistance. So, pharmaceutical assistance has to become part of a comprehensive policy. (...) So I reckon that the positive side of the FP is to facilitate access, but at the same time it is contradictory because of separate dispensing and care (Interview 8; 12.3).*

Although access has improved with the FP, other activities that should complement the dispensation of drugs were not part of the programme. State and municipal health secretaries expected that the broad range of activities related to pharmaceutical assistance might be partly addressed by including at least pharmaceutical and healthcare advice. As the following quote suggests, many patients in need of medicines were satisfied with the FP because it was the first time they had consistent access to medicines. However, they were unaware that pharmaceutical care is within the scope of SUS and therefore should be provided by FP pharmacies:

*So the government says that the population is very satisfied. Obviously they are very satisfied because they have always fought desperately to have access [to medicines]. What the population does not know is that they have the right to a qualified service of pharmaceutical attention beyond the access to medicines. The population does not know that (Interview 17; 7.2).*

The inadequacy of access before the implementation of the FP is raised as a problem in the quote above, as is criticism of the pharmaceutical service provided by popular pharmacies. The interviewee attributed patients' satisfaction with the FP to the availability of medicines compared with the previously experienced lack of access. The same interviewee went further and argued that the FP represents a step backwards in the process of integrating medication and overall health care. He explained that although patients are satisfied by the fact that they can receive the drug without payment, they are missing the guidance and pharmaceutical care that they should receive to help them use the medication better, as is illustrated in the next extract:

*The patient goes to a Popular Pharmacy, receives the medicine, does not pay a penny, and leaves highly satisfied. But it is likely that he [sic] takes the medication incorrectly, does not respect the recommendations on interaction with food, does not follow the schedule right, was not warned about the side effects that can arise, among other things. I think it is absurd what the government is doing. We are severe critics of this programme and we are*

*trying to change that, but we know that once things start it is very difficult to change them (Interview 17; 7.3).*

The interviewee defended the conviction that the pharmacy should provide guidance on the best way to take the medicines to gain the best effect of the treatment or at least how to avoid incorrect use.

In contrast to such strong criticism from this municipal agent, Ministry of Health officials argue that SUS is also not providing pharmaceutical care for patients. This is best illustrated by the following quote:

*Now of course, you have people who used to go to the Basic Health Unit to get their drugs, but now because they have a [FP] pharmacy around the corner they will change [from public to private]. Well, is this bad? If we had UBS<sup>145</sup>s with a different approach from those private pharmacies, this trade would be bad. If [at the UBS] we had guidelines for patients regarding medication and other supportive therapies for hypertensive patients we could criticise the FP. But actually in UBSs they do nothing different... They also only dispense medicines (Interview 18; 9.2).*

The Ministry of Health refuted the criticism by stating that the basic health units are not practicing pharmaceutical assistance in the broad sense either, i.e. SUS pharmacies are only dispensing medicines like the FP does. Here, to better assess the two sides of this discussion about the pharmaceutical care in SUS or FP pharmacies, it is important to recall some of the points discussed in Chapter Six related to the difficulties in implementing pharmaceutical assistance in municipalities. Health secretaries described many barriers to the development of pharmaceutical assistance after decentralisation. One of them was human resources: they pointed out that it was difficult to fulfil the requirement of having a pharmacist in each SUS pharmacy. It is plausible to infer that SUS pharmacies without pharmacists are only distributing medicines, and therefore in this case there is no integration between health care and medicines. But, behind the health secretaries' criticism is the claim that the money invested in the FP should be given to states and municipalities to develop SUS pharmaceutical assistance.

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<sup>145</sup> UBS- Unidade Básica de Saúde or Primary Care Unit

Another Ministry of Health official goes even further by stating that the issue of integrating care and distribution could be more easily solved in the private sector than in the SUS: "*it is easier to qualify access in the private network*" (Interview 19). This understanding that the private sector could solve this problem with greater agility is based on the satisfactory performance shown by private partners throughout the process of implementation of the FP. In my view, the rapid response usually associated with private partners is related to their economic interest in expanding their clientele<sup>146</sup>. Judging from the development of the programme, the financial resources invested and the political dividends that have been collected by the federal level, all lead me to believe that qualification of pharmaceutical care and integration with primary health care will be the next step to be pursued with the help of private partners. FP development has followed an incremental course: first co-payment in the public arm; then expansion to the private pharmacy network, and finally the distribution of medicines free of charge. These three stages dealt with the issue of availability of medicines. How distribution of medicines and SUS health care will work together is still undecided. It is still not clear how the federal government intends to achieve this solution. But, it is unquestionable that the FP programme has changed the landscape of basic pharmaceutical assistance and it is very likely that the programme will be part of the solution to the problem of integrating distribution and care.

### **7.5.3 Top-down policy-making**

The policy-making route adopted in the FP was unusual considering the negotiation and agreement forums provided within the SUS. As remarked, the FP came about as part of the electoral platform of presidential elections. The programme design and implementation strategy have not gone through discussions and agreements with subnational actors. Interviewees expressed clearly that the creation of the programme was a decision stemming from the President of the Republic and that he pressed for its implementation. It was submitted and approved in SUS forums without having been discussed extensively. The strategy chosen to improve access did not take into account the decentralisation and SUS policy-making mechanisms nor did it include SUS in the implementation. CONASS, CONASEMS and CNS advocated that investments and efforts to improve access should be invested in SUS basic pharmaceutical programmes instead of in the FP. This is illustrated in the quote below:

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<sup>146</sup> ABRAFARMA (Brazilian Association of Pharmacies and Drugstores Networks) celebrated the vigorous evolution of the pharmaceutical market in Brazil, which increased sales volume by 82% from 2008 to 2011 (R\$ 24 million in 2008 and R\$ 43.9 billion in 2011). One of the factors that favoured their growth, according to ABRAFARMA, was the migration of SUS patients to FP accredited pharmacies. Source: [www.abrafarma.com.br](http://www.abrafarma.com.br)

*So, in CONASEMS currently there is a significant discussion about this programme. This specific case of the FP, it was a programme that was a decision by the President of the Republic, President Lula, to ensure access to medicines at prices much lower than those charged by the market. We're not against that goal of the FP, but we always understood that this could have been done through SUS. Today that programme is consolidated throughout Brazil and eventually contributing to improve access to medicines in the municipalities that have the FP (Interview 8; 12.2).*

The goals and the efficiency in improving access to medicines are not in question, but the way to put them into practice is. There is consensus amongst subnational actors that the improvement in access should be made via SUS. This argument also encapsulates the notion of FP not being part of SUS. In the accounts I found other elements which, in my view, are related to this notion of separation. Presenting the programme as a presidential decision (not discussed with subnational actors, as other SUS programmes are), implemented by means of dedicated facilities ('owned' pharmacies) combined with private partners, has contributed to the image of a programme detached from SUS.

Comparisons between FP and SUS facilities were a recurrent theme in my interviewees' accounts, as well as the perception of different standards within the SUS. The respondent, in the following quote, refers to 'owned' FP pharmacies that have standards set at the federal level. As it is a centralised programme, the standards, guidelines and management are controlled by FIOCRUZ, the federal foundation that administers the public arm of the programme. In order to fulfil these standards, the municipality receives a certain amount of money to construct/refurbish the pharmacy. This process results in 'high quality' pharmacies, as portrayed by the interviewee, contrasting with the precarious conditions in SUS:

*Furthermore, the municipal health secretary has no control over the FP-owned pharmacy. Who controls everything, even the officials who are in fact employees of the municipality, is FIOCRUZ. (...)Why does everything have to be high quality for the FP, while I have difficulties in UBS. You should not have all the financial resources invested in FP if basic pharmacies in primary care service are precarious. It's like there's a disconnection, they created a programme that works separated from the primary health care as a whole (Interview 10; 7.3).*

The difference in standards applied to SUS and the FP, and the independence of the federal foundation, pointed out by this municipal health secretary, supports the notion that the programme was designed to work outside SUS jurisdiction. In my view, this detachment, whether deliberately constructed or the result of circumstances, contributed to dismissing the possible reactions against federal interference in the autonomy of municipalities to manage the provision of basic medicines. I will develop this claim further in the next section.

In this section we saw how the federal government has dealt with the criticism that was openly posed by state and municipal actors: co-payment, lack of integration with SUS, and top-down policy-making. In the next section I will discuss how the federal government avoided a debate about recentralisation, which could cause major opposition from municipal and state health secretaries, mayors and governors.

## **7.6 How the debate about recentralisation was avoided**

At this point it is worth reflecting why the centralised nature of the FP programme was not opposed by municipal and state health secretariats considering that the programme has reduced their role within the provision of basic medicines. The improvement in access that followed FP implementation gave the federal government the justification to keep investing in the programme. The federal government has also managed to avoid major opposition to a centralised programme (FP) within a decentralised environment. My interviews suggest that the federal government used the right to health and medicines to shield the programme and to head off questions about recentralisation. With the same purpose, the government did not change the responsibilities of municipalities regarding basic medicines, and used separate financial resources to fund the FP. In order to explain this claim I will discuss these three aspects: the ‘right to health’ constitutional principle; the separate financial resources; and the unchanged legal framework regarding the responsibilities of subnational actors.

Overall, in my study the FP is well rated by interviewees, who all agreed that the FP improved access to medicines. There is no dispute about FP achievements in terms of availability of medicines. Each interviewee, even those that had reservations regarding the way the programme was created and implemented, agrees on the benefits to access brought about by the FP. Although there was general agreement on the benefits of the programme, it is possible to distinguish two groups that have different views: the state and municipal health secretaries, and the Ministry of

Health officials. State and municipal secretaries were ambivalent because, while they perceived advances in access to medicines, they also argued that that improvement in access could have been achieved via SUS if it had received more money. Ministry of Health officials focused mainly on the advantages that the FP brought to the population. In general, those officials argued that the programme allowed citizens to obtain their medication in many facilities distributed around the country, where the medicines were always available; contrasting with the frequent drug shortage experienced in SUS pharmacies. Acknowledgment that these two groups of actors stand in different camps is important to understand the dynamics of the changes that took place when the FP was implemented.

The ambivalent position of health secretaries helps to understand the expansion of the FP that took place simultaneously with the decentralisation of SUS. Their weak and inconsistent opposition, in my view, have allowed the FP programme to develop. In my research, the accounts have suggested that the perceived benefits of the FP helped to neutralise their opposition. In the next quote a former municipal health secretary and current Ministry of Health official expressed his reservations regarding the strategy of co-payment, which “violates certain principles”; he is referring to the right to universal and free of charge access to medicine. But he recognized that the FP facilitates citizens’ access to medicines, and admits that they are not interested in how access was achieved:

*So when you find a mechanism to reduce the difficulty of access ... Often, Brazilian citizens do not distinguish whether this mechanism violates certain principles. They actually want their rights to be guaranteed if their right is being guaranteed, that is what matters (Interview15; 10.2).*

Here it is important to note that this Ministry of Health official articulated a view that corresponds with the official view of the federal government. This respondent uses the fundamental ‘right to health’ principle stipulated in the Brazilian Constitution. In this case, the right to access to medicines justifies the implementation of the programme. The official suggests that to ensure the population’s right to medicines it does not matter if the FP is not in accordance with SUS precepts. This notion advocated by the federal level that the FP was helping to guarantee citizens’ rights to health made it difficult for state and municipal levels to position themselves against the initiative.

Another important aspect to this discussion on the right to health is that the FP programme was portrayed as able extend the coverage of drug provision. Prior to the FP, provision was split into private or public spheres with separate rules, patients and prescriptions. SUS patients would

receive their medication in SUS units, while non-SUS patients (those that have health plans) should buy theirs in community pharmacies. The FP, in contrast, does not distinguish between SUS or private health plan patients: both can have their medicines dispensed from the same facilities. The next quote illustrates the importance of providing the medicines needed, whether patients come from private or public services:

*I believe that this initiative [FP] did not come to complement [the distribution of medicines], it came to universalise. I do not want to know where they [the patients] were diagnosed with hypertension or diabetes. The citizen can go to UBS<sup>147</sup> or FP to have their medicine dispensed and use it (Interview 18; 9.3).*

The term “universalise”<sup>148</sup> means that the FP dispenses medicines for patients coming from either SUS or private services (SUS pharmacies, on the contrary, only distribute medicines to patients holding a SUS prescription). Here, again the FP initiative is portrayed by a Ministry of Health official as a way of fulfilling rights enshrined in the 1988 Constitution. In short, the federal government implemented the free distribution of medicines (third stage FP) with the promise of “universal” access to medicines. The rapid expansion of the FP programme suggested that the decentralised provision was not able to fulfil the needs, although SUS only had to provide basic medicines for citizens within low-income strata. Combining those ideas of inefficiency and limited scope, the federal government presented the FP as the alternative to provide basic medicines for all citizens, as required by the constitution. This image, propagated by the federal level, allowed local health authorities to support the FP, even though the programme was not in line with the fundamental principle of free medicine from SUS. The idea was that the programme served the purpose of ensuring access to medicines, which is a right. Evoking this fundamental right, to health and medicines, and prioritising it, imbued the FP with enough importance to reduce the effect of any resistances that might appear. The speech of President Dilma Rousseff at the United Nations General Assembly, in 2011, evidenced the importance of the programme within the federal government and illustrates its link to the promotion of health rights for all:

*Brazil advocates access to medicines as part of the human right to health. We know it's a strategic element for social inclusion, for the pursuit of equity and the strengthening of public health systems. One of the first actions of my administration was to increase access to medicines for patients with hypertension and diabetes in the National Health System. We are providing free of charge drugs for these diseases, specifically diabetes and*

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<sup>147</sup> UBS-Unidade Básica de Saúde is the primary care unit.

<sup>148</sup> This term was also used by the president of the republic, Dilma Rousseff, when she launched the third stage of the FP programme.

*hypertension. The health programme, Health is Priceless distributes free of charge medication through partnerships with more than 20 000 public and private pharmacies.*<sup>149</sup>

As a result of the belief that access to medication was part of the human right to health, the Government had increased access to medication for patients with hypertension and diabetes. Although President Dilma's speech does not emphasise the contribution of the public and the private arm, figure 7.1 showed that just 560 of about 20,000 pharmacies were 'owned'.

The second aspect that helps to explain the success of the government's strategy is the financing arrangement designed for the FP. The programme was regarded as a "bonus" by health secretaries. This term was used by one of the interviewees, and I think it successfully reflects the perception of Secretaries of Health. The FP distributes medicines without any further costs to the municipality. The federal level sends dedicated resources to install and maintain the public arm, and pays for the medicines dispensed by the private arm of the programme. The funding strategy used by the federal government has allowed municipalities to benefit from the improvement in the provision of medicines without any financial drawback. As stated by a Ministry of Health official, municipal and state level actors placed no restriction on FP pharmacies, since there were no changes regarding the money allocated to finance basic pharmaceutical assistance within SUS. Therefore, the Ministry of Health made clear the distinction between the financial resources that fund basic medicines for SUS pharmaceutical assistance and those for the FP programme. Policy documents state that the funds to finance the FP should not be mixed with those monies allocated to purchase medicines in SUS. Federal funds transferred to States, the Federal District and Municipalities for co-funding basic medicines were not affected by the FP (Ministerio da Saude, 2005b).

Indeed, the interviews suggested that the fact that the money for the FP does not come from the budget of basic pharmaceutical assistance is an important characteristic of the programme, and this has contributed to shaping the way the programme is perceived. Accounts of some interviewees suggest that the FP programme is considered an initiative unconnected to SUS. In the context of decentralisation, this perception of the FP as something detached from SUS may be regarded as serving the purposes of the Ministry of Health. This disconnection between the FP and SUS could help to fend off criticism and opposition that could be raised to the centralised character of the programme. Keeping FP and SUS basic pharmaceutical assistance in separate spheres has helped

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<sup>149</sup> This quote is part of President Dilma Rousseff's speech at the Sixty-sixth United Nations General Assembly, which opened a high level meeting on the Prevention and Control of Non-communicable Diseases, in New York on September 29<sup>th</sup>, 2011.

the federal government to avoid comparative analysis that might highlight similarities between the goals of both initiatives and show up a contradiction in the strategies used. This comparison would evidence that the federal government, ignoring all pacts and regulations negotiated in SUS agreement forums regarding decentralisation, i.e. bypassing subnational levels, has created a centralised programme in partnership with the private sector.

The third aspect, which in my view was important to the acceptance of the initiative, was its legal aspect. The federal level showed state and municipal level actors that legislation or regulation regarding basic pharmaceutical assistance would remain unchanged. The legal framework which governs pharmaceutical assistance was not amended or changed after the launch of the FP programme. Their roles and responsibilities remained the same, as did their autonomy to manage health services and the financial resources related to them. Therefore, if regulation and financing regarding the decentralised provision of medicines was not changed, they could not talk about recentralisation. In fact, in the interviews, none of the health secretaries has engaged in the discussion of recentralisation. This became apparent when the interviewees were asked for their opinion of the FP programme and its federal control. Even when probed they did not talk about recentralisation. In their view, SUS provision of basic medicines is still decentralised. This perspective adopted by state and municipal secretaries helps to understand why the centralised characteristic of the FP has not been on the agenda of SUS national forums.

By not changing the responsibilities and financial resources of municipalities related to the provision of basic medicines and by implementing a parallel system of distribution of drugs the federal government was skilful in avoiding confrontation with subnational actors. Taking into consideration FP development, I would argue that the federal government strategically kept the FP and basic pharmaceutical assistance in two separate spheres. By so doing, it diverted the attention of subnational actors from the centralised character of the FP programme. To officially exclude states and municipalities from the management of the basic medicines could give rise to strong opposition and would be regarded, most certainly, as a loss of the power achieved by decentralisation. It is reasonable to assume that if the FP became part of SUS the distribution of funds would change. Municipalities would not receive the resources to buy the drugs distributed by FP. This would reduce the revenue of the municipality. Conversely, if FP were incorporated by SUS, the control of basic pharmaceutical assistance would be transferred to the federal level, i.e. it would be clear recentralisation.

As this chapter draws to a close I would like to remark that at present, the FP is fully consolidated. Due to its undeniable achievement in improving availability of drugs, I believe that going back is not an expected option either from the federal side or from the subnational actors. Despite their negative comments, health secretaries recognise the importance of the programme in providing access to basic medicines within primary care.

## **7.7 Conclusions**

In this chapter I drew a picture of how state and municipal health secretariats regarded the changes in the management of medicine provision introduced by the FP programme. I discussed how recentralisation, represented by the FP programme, has impacted on provision of basic medicines.

Three of the participants provided narratives that indicated the influence of the President of the Republic on the creation and expansion of the FP programme. The rationale for implementing this centralised programme was to provide drugs at subsidised prices to those patients with low-cost private health plans, i.e. non-SUS patients. Underlying the rationale for expanding the coverage is the notion that availability of medicines was insufficient in SUS pharmacies. In their accounts, participants reflected on the role of the FP programme in providing basic medicines. Although they have reservations about and criticisms of users' co-payment introduced by the FP, they recognized the improvement in the availability of medicines provided by the programme. As a consequence of this better availability, SUS patients are migrating to the FP. According to participants, this migration is approved and even encouraged by some municipal health secretaries. As the FP develops and more patients use the programme and consequently fail to use SUS, this could cause the municipalities to stop buying those drugs that are distributed by FP. Consequently, this could lead to a weakening of public service and result in dependence of the private sector.

The participants expressed dissatisfaction with the choice of the federal government regarding the partnership of the FP with the private sector. The programme has received major investments that allowed its rapid expansion throughout the country via the community pharmacies network. In their accounts, respondents advocate that those investments should go to SUS.

Respondents have identified in the FP's private partner the characteristics needed to solve the failures of SUS basic pharmaceutical assistance. In fact, with the implementation of the FP, the

federal government has managed to remove almost all obstacles and barriers to the development of SUS basic pharmaceutical assistance.

Additionally, the interviews suggested that the federal government avoided direct confrontation with state and municipal health secretaries when it implemented and expanded the FP programme. The FP programme introduced new mechanisms and new actors to the process of public delivery of essential medicines, but the state and municipal levels were excluded from its design and implementation. This exclusion goes against the entire trajectory of decentralisation that had been built up over the years in pharmaceutical assistance and, overall, in the Brazilian public health system. Considering all the mechanisms and instances of agreement provided by the decentralised framework of pharmaceutical assistance, there was a potential for confrontations with the excluded actors. I argue that the federal government's success in avoiding major opposition is due to three factors: the unchanged legal framework regarding the responsibilities of subnational actors; the separate financial resources used to fund the FP and SUS pharmaceutical assistance, and the 'right to health' principle evoked to justify the programme.

To conclude this chapter I would say that FP deeply impacted the decentralised provision of basic medicines, mainly due to the inclusion of the private sector in the programme. The community pharmacies network allowed the programme to develop rapidly around the country. This strong presence of FP facilities and the consistent availability of medicines resulted in migration of SUS patients to the programme. In other words, these patients are no longer receiving drugs in SUS units. Now they receive those drugs from community pharmacies accredited in a centralised programme. Reflecting how this situation could evolve, I would argue that the provision of basic medicines via the private arm of the FP programme would, eventually, replace provision in SUS facilities. My assessment is based on the increasing financial resources invested in the community pharmacies network and the political commitment devoted to the programme.

## **CHAPTER EIGHT**

### **CONCLUSIONS**

#### **8.1. Introduction**

In this thesis I explored how decentralisation has affected the public provision of basic medicines in Brazil in the views of health secretaries and Ministry of Health officials. Decentralisation is one of the SUS pillars and was implemented in 2005 with the aim of solving shortages in public provision of basic medicines. Simultaneously to the decentralisation move, however, the federal government invested heavily in a centralised programme to distribute basic medicines.

My work was structured around four main questions. First, I investigated how the process of decentralisation developed and who the actors involved were. This led me to my second point of research which was the examination of power dynamics involved in the federative relationships related to the management of pharmaceutical assistance, and the role of federal entities in the improvement of access to medicines. The third aspect I explored was the situation of access to basic medicines after decentralisation through the lens of the actors involved in the design and implementation of the policies in the field. The last aspect I focused on was the emergence of a programme which aimed to improve public provision of basic medicines controlled by the federal government and delivered in partnership with the private sector.

In this concluding chapter, in sections 8.2 to 8.5 I will review these four areas, summarising and contextualising my main findings to answer my research questions. The subsequent sections present the contributions and limitations of the study, suggestions for future research and my concluding remarks.

#### **8.2 Decentralisation and centralisation of public provision of basic medicines**

Exploring the question of how the decentralisation of basic pharmaceutical assistance took place, I started by investigating how the process was triggered and the motivating factors behind it.

### **Call for changes: main actors and motivations**

The narratives of my interviewees revealed that demands for decentralisation originated in municipal and state tiers. Municipal and state health secretaries represented in CONASEMS and CONASS, respectively, took a leading role in the process of decentralisation. This pattern is consistent with Falleti's (2010:152) assessment of the key role of subnational actors in the decentralisation process in Brazil.

Difficulties in providing basic medicines to SUS patients were pointed out by health secretaries as the primary reason for demanding decentralisation. The main problems reported by the secretaries in my interviews concerned the inadequacy of medicines (such as the type and quantities of supplied drugs) and logistic problems that resulted in constant failure or delay in delivering drugs to the municipalities. These two problems had a negative impact on access and were associated with a shortage in medicines. My interviewees suggested that the lack of suitable medicines to meet local needs resulted from the inability of the Ministry of Health to accommodate the epidemiological particularities of each region when planning which drugs should be purchased. In fact, before the decentralisation of basic pharmaceutical assistance, the Ministry of Health distributed a standard set of medicines to all municipalities regardless of the particular needs of the region.

In this scenario, demands for decentralisation were based on the expectation that redistributing responsibilities, decision-maker powers and resources would facilitate local problem-solving regarding the provision of medicines. The pursuit of decentralisation by health secretaries found support within the Ministry of Health due to the difficulties the latter had to operate the distribution of medicines throughout the country. Thus, the three tiers of government each had different reasons for supporting decentralisation changes.

Another aspect that motivated health secretaries' demands was linked to the prior decentralisation of health care, implemented after the health reform and creation of SUS in 1988. With that reform, municipalities were responsible for the management and delivery of health services. Therefore, they expected that the management of the supply of medicines used in primary care should also be their responsibility. According to the health secretaries I interviewed, decentralisation of pharmaceutical assistance was the 'natural' way to follow. The secretaries pointed out the necessity of reorganising and integrating the provision of basic medicines into local SUS services. Unlike the decentralisation of health care which started in 1988, decentralisation of pharmaceutical assistance

has no well defined point that marks its origin. In basic pharmaceutical assistance, according to my interviewees, the case for decentralisation was built gradually. The first significant step, as the narratives revealed, was to bring pharmaceutical assistance to the policy arena.

### **National Medicines Policy provided opportunity for changes**

Based on my interview data it was not possible to establish exactly when calls for decentralisation of basic pharmaceutical assistance began. What could be established, however, was that in 1998, with the enactment of the National Medicines Policy (NMP), the distribution of responsibilities to subnational actors to manage the provision of basic medicines was officially stipulated. According to the accounts of my interviewees, from the moment that decentralisation was incorporated into the legal framework, the subject became part of SUS negotiating agenda. From this point onwards, shortage of medicines began to be discussed in SUS agreement forums (both at subnational and federal level, CIB and CIT, respectively).

### **Implementation of decentralisation was a gradual and negotiated process**

The circumstances that allowed the provision of basic medicines to be decentralised resulted, at least partially, from the 1988 health reform. The new set-up that ended in municipalisation of health care empowered health secretaries and legitimated their demands for autonomy to manage the basic pharmaceutical assistance. Although since 1998 decentralisation was part of the NMP, narratives indicated that decentralisation of pharmaceutical assistance entailed a long process of negotiations until 2005 when financial resources actually started to be transferred to municipalities. In the meantime, discrete and incremental changes were introduced. The series of negotiations on how to implement decentralisation resulted in agreements that did not substitute previous policies at once but gradually added new responsibilities to subnational levels. This policy-making pattern that I observed in my work was pointed out by Schmitter as typical of the policy process in Brazil. More than forty years ago, Schmitter (1971:256) argued that “[p]olicy in Brazil changes by accretion rather than by substitution”.

Another factor that interfered in the decentralisation of pharmaceutical assistance was related to the expectations and understandings of decentralisation held by the actors involved. As discussed in Chapter Two, and well explored by Saltman *et al.* (2007:10), there is no common definition or understanding of decentralisation, and it could mean various things to different people. This also proved to be true in the case of decentralisation of pharmaceutical assistance explored in my thesis. Decentralisation was understood differently by the Ministry of Health and by the health secretaries.

To the Ministry of Health officials, decentralisation meant distributing funds to municipalities and states for purchasing medicines. This transfer of financial resources by the federal level, can, in fact, be regarded as the last step in the process of decentralisation. In contrast to the willingness to change voiced by Ministry of Health officials, the distribution of funds only started from 2005 onwards, as mentioned above. Falletti (2010:177) also highlighted the struggle for federal transfers in the decentralisation process in Brazil. Referring to the decentralisation of the health sector, she argued that “national authorities resisted the decentralization of funds”. Hence, while from the federal government’s point of view decentralisation meant transferring funds, in the case of state and municipal actors, decentralisation meant receiving (or assuming) the autonomy to decide which medicines to buy and participation in decisions concerning medicine policy in SUS forums of negotiation. The restricted scope of decentralisation in the views of the Ministry of Health contrasted with wider subnational demands, which included redistribution of responsibilities, decision-maker power and resources. Therefore, both centre and periphery held different understandings and expectations related to decentralisation, which might have influenced the process and timing of its implementation.

Although decentralisation is one of the pillars of SUS, in my interview data it was possible to identify differences between the views of federal and subnational levels on the decision of whether to maintain centralised provision of basic medicines or to decentralise it. On the one hand, subnational actors considered that decentralising basic pharmaceutical assistance was the right decision and it represented a one-way process, i.e. there was no place for reversion on that choice. For state and municipal secretaries, basic pharmaceutical assistance should be managed by the municipal level regardless of the results and the federal level should provide support to make possible improvements in municipal management. On the other hand, for the Ministry of Health, centralisation or decentralisation was an interchangeable approach depending on the results obtained with regards to costs and economies of scale.

### **Regional differences shaped the implementation**

Regarding the question of how decentralisation took place, accounts of my interviewees suggested that regional differences are important to understand patterns of decentralisation development. Such disparities motivated but also limited the implementation of the decentralised approach in some regions. In other places, however, innovative solutions in the provision of medicines emerged as a result of decentralisation.

As discussed above, epidemiological differences between different regions in the country also motivated decentralisation. The fact that the medicines supplied were often unsuitable for local epidemiological conditions was a problem experienced by many municipalities. According to the accounts of my interviewees, this issue was widespread and seemed to favour decentralisation being included in the agenda at SUS negotiation forums, receiving much support from subnational actors. Nevertheless, when decentralisation actually started to be implemented, it caused many problems in less developed regions. These places faced more difficulties in managing pharmaceutical assistance because they lacked human resources and physical infrastructure, and had poor administrative capacity. Accounts of my interviewees suggested that, in small municipalities, despite some advances in the availability of medicines over the years, these barriers of unpreparedness are still preventing further improvement in access to medicines. As my interviewees suggested, although municipalities asked for autonomy to choose which medicines to buy, at the beginning they continued to buy the same list of medicines they had claimed inadequate when sent by the federal level.

In the negotiations to establish the implementation, options on how to conduct decentralisation were agreed between the three tiers. There were two types or stages of decentralisation, depending on where responsibilities and power were concentrated: municipal (or complete decentralisation), and state (or partial decentralisation). In the latter option, municipalities could opt to leave the responsibility for managing pharmaceutical assistance in the hands of the state, but would retain the prerogative to determine the types and quantities of medications the state should acquire and distribute. As discussed in Chapter Four, this option seems to have emerged from the previous experience with decentralisation of health services,<sup>150</sup> and it preserved the power of the municipalities to choose the medicines they needed. At the same time, partial decentralisation does not burden them with bureaucratic tasks, such as public bidding, which would require highly qualified human resources that are often not available in small municipalities. The state level would act as a 'buffer' to absorb more complex tasks by balancing the deficiencies of municipalities. This arrangement, however, was not sufficient to resolve regional differences. On the contrary, the possibility of partially decentralising pharmaceutical assistance, an alternative that could be seen as a solution to the diversity of situations in Brazilian municipalities, ended up contributing to increase regional disparities. States that already had the best structures in terms of health services were also those most committed to the process of decentralisation, leading to better support for municipalities within their jurisdiction, as was the case with Paraná, Minas Gerais and São Paulo, although the latter to a lesser extent.

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<sup>150</sup> As discussed in Chapter One, decentralisation processes of health care used gradual levels of complexity in terms of service delivery in an accreditation process to enable municipalities to join decentralisation.

The option for partial decentralisation was not available to all, though. The accounts of my interviewees showed that certain municipalities had no such choice (even though partial decentralisation would be the most appropriate option for small municipalities). In these places, local authorities had to take responsibility for the full cycle of basic pharmaceutical assistance because the state level did not join a partial decentralisation scheme. There might be more than one explanation for the fact that some states did not engage in making partial decentralisation possible. Considering that this lack of support to municipalities was present usually in less developed regions, I would argue that it had resulted from unpreparedness at the state level. In less developed regions, states suffer, to varying degrees, from the same problems faced by their municipalities, in terms of structure and administrative capability. Thus, in these cases, neither states nor municipalities were prepared to take responsibility for the provision of basic medicines.

At this point, it is important to take a closer look at the implications of this lack of preparedness for decentralised duties in the perpetuation of regional disparities. Corroborating what has already been described in other studies, data from my interviews suggested that the decentralisation of basic pharmaceutical assistance in Brazil has not helped to reduce disparities between regions. This finding is consistent with Bankauskaite and Saltman's (2007:16) observations regarding decentralisation in European countries. Decentralisation caused interruptions to the Ministry of Health's distribution of basic medicines, which made less developed regions responsible for tasks for which they were unprepared. One Ministry of Health official I interviewed considered that, in some cases, decentralisation was practically 'forced' upon certain municipalities because although some of them were not ready to take on the decentralised tasks, the option of having basic medicines distributed by the federal government was no longer available. In those situations where partial decentralisation was not available, the double burden of having neither state support nor structural conditions to perform the decentralised duties contributed to the worsening of the situation of these municipalities. The perception of my interviewees was that, in poor regions, instead of reducing disparities, decentralisation of pharmaceutical assistance has contributed to the deterioration in access to medicines and thus contributed to increased inequality. This perception is corroborated by the view expressed by the Brazilian political scientist Marta Arretche (2012:11). Referring to modern democratic states, she remarks that, in general, regional differences in the provision of services could be regarded as a consequence of the authority being devolved to subnational governments to decide on their own policies. According to her, this can lead to inequalities in the provision of services to citizens living in different localities in the same country.

In contrast, municipalities located in states with more structured health services, in general, had the option of having partially decentralised pharmaceutical assistance. In these places, the usual problems of small and medium municipalities related to lack of administrative capacity, human resources and physical structure were absorbed by the state level, and decentralisation was perceived by interviewees as beneficial to access. In these states, the power and resources distributed by decentralisation were used to deploy innovative solutions in the management of pharmaceutical assistance. Paraná, for example, created the Paraná Consortium of Medicines to manage pharmaceutical assistance. This initiative was pointed out by members of CONASS, CONASEMS and by Ministry of Health officials as the most successful example of good pharmaceutical assistance. Moreover, the initiative was perceived as an example to be followed. This case led me to a reflection on the peculiarities of the implementation of decentralisation across the country and their influence on the availability of medicines at the local level.

In the successful initiative in Paraná, decentralisation was partial, i.e. it stopped at state level. This means that the state receives federal and municipal contributions for pharmaceutical assistance funding, and was responsible for planning, purchasing and distributing basic medicines. The state in this case played a key role in the emergence of this solution which resulted in improving access to medicines. The coordination of the state and the existence of adequate administrative structure were critical to the success of the initiative. The difficulties and limitations of small municipalities were, in this case, outweighed with the help of the state level.

These variations in the results achieved with decentralisation, which I identified as being directly associated with the degree of development of the region, indicates that there is no single approach that could solve issues of access to basic medicines. In fact, as Vrangbaek (2007) argues, decentralisation often results in differences in services and quality across decentralised units depending on local capacity which could reduce equity and fairness. I discussed examples showing contrasting results of decentralisation which, I argue, are linked to regional differences in terms of administrative capacity and the role performed by the state level. The discussion of whether there is an appropriate degree or level of decentralisation is another aspect where there is no consensus within the literature on decentralisation. The regional disparities and their influence on access that I found in my work confirm the conclusion that there is no universal solution or model to be followed. My findings are consistent with Vrangbaek's (2007) suggestion that the challenge in decentralisation and centralisation processes in health services is to find an optimal mix of central and decentralised management.

### **8.3 Federative relationships in a decentralised setting**

The process of decentralisation of pharmaceutical assistance involved federative relationships and negotiations in SUS forums of agreement, namely CIB and CIT. My question was how these federative relationships affected the decentralisation of public provision of basic medicines. It is worth noting that decentralisation was not compulsory since federated entities have administrative, political and financial autonomy<sup>151</sup> within their jurisdiction. Therefore, states and municipalities had to be persuaded by the federal level to join the process, which was similar to what had occurred in the decentralisation of health care more broadly.

#### **Roles and responsibilities: coordination, interdependence and autonomy**

The definition of roles and responsibilities of each level of government in the management of basic pharmaceutical assistance took years to clarify and put into practice (even though the pattern of responsibilities of each tier overlaps the ones of primary care services). As a result of the long process of agreement, coordination and technical assistance became federal and state duties, whereas municipalities were in charge of service delivery. Basic pharmaceutical assistance, like primary care, is co-funded by federal, state and municipal level. In this regard, the process of negotiations resulted in an agreement which stipulated the percentage of funds that each federal entity had to contribute, and the roles and responsibilities of each level.

In those situations where decentralisation was complete, federal and state contributions should be transferred to the municipality for the purchasing of medicines. In partial decentralisation, it is the state level which should receive federal and counterpart contributions for purchasing basic medicines. Thus, the success or failure of decentralised initiatives depended on the fulfilment of pacts between federal entities. As I will discuss next, my research revealed that non-compliance with the pacts negatively influenced the decentralised provision of medicines, and the enforcement of compliance was hindered by the federative arrangement.

#### **Disruption of pacts: failures and lack of accountability**

States failing to transfer funds was the main issue in the accounts of municipal secretaries with regards to federative relationships and pharmaceutical assistance. These disruptions affected the

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<sup>151</sup> The financial autonomy is limited, but municipalities and states have a certain degree of autonomy to rise and expend funds. These rules are provided in the Constitution.

provision of medicines by municipalities regardless of whether they opted for partial or complete decentralisation.

In cases where decentralisation was complete, when the state failed in sending its financial contribution, municipalities had the federal share to purchase the medicines. In partial decentralisation the drawback in the case of a state failure was even greater. Those municipalities did not receive the drugs that should be distributed by the state, and could not afford to acquire them. All funds to purchase basic medicines, in this case, were in the state's hands. Those failures were portrayed as difficult to solve, though. As I discussed in Chapter Five, there is no effective mechanism to enforce compliance with the agreements signed. The penalty stipulated for non-compliance is the interruption of federal funds transfers to health. The punishment, however, if enforced, would further undermine the whole municipal health system, not only the provision of basic medicines.<sup>152</sup> In fact, as far as my research showed, this measure was never used. Nonetheless, if there is no penalty these situations can persist for long periods, compromising the availability of basic medicines in the municipalities affected. According to my findings, even in São Paulo state, which is probably the most developed state in the country, there was a situation of failures in the co-funding of the basic pharmaceutical assistance which persisted for at least two years, in 2010 and 2011. I would argue that the federative arrangement (particularly the interdependence in the co-funding) and autonomy granted in the Constitution, contribute to perpetuating the problem of accountability; there is no applicable countermeasure that could be taken for this situation.

These issues of accountability, transfer of funds, and non-compliance with agreements, as my interviewees suggested, continuously occupied the agenda of SUS negotiation forums. According to the perception of one Ministry of Health official who participated in CIB meetings in various regions of the country for almost two years, this preponderance of matters relating to financial resources prevented other subjects from being discussed in these forums.<sup>153</sup> Thus, municipalities are prevented from advancing in the discussion and negotiation of other issues related to pharmaceutical assistance, which, consequently, will not reach CIT's agenda.

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<sup>152</sup> Health is co-funded by the three government tiers; interruption in federal transfer of funds would compromise the delivery of health services in the municipalities.

<sup>153</sup> There are steps to be followed until a theme or subject reaches the CIT's agenda, which is the last step in the negotiations between the federal entities that are part of SUS. As discussed in Chapter One, the first step in general entails the discussion of this issue in the municipality and then, if deemed important, this is brought to the agenda of the CIB, which is the ultimate forum within the state. The CIB brings together representatives of the state health secretariat and the municipalities within the area.

### **Ideology and party political influences**

In my work, partisan political influence was another aspect of federative relationship that had repercussions on the course taken, and on the results achieved by the decentralisation of basic pharmaceutical assistance. My interviewees associated the high turnover of officials in the executive branch with limited progress in the implementation of the decentralised pharmaceutical assistance.<sup>154</sup>

According to accounts from my interviewees, the lack of continuity in work teams was one of the consequences of partisan political influence. Interviewees reasoned that in the states where partisan political influence in the choice of leaders was less frequent, health work teams remained for longer in the health secretariat. Permanence of staff was associated with incremental and steady development of the pharmaceutical assistance, which in turn was translated into improvements in access to medicines. The states of Ceará and Paraná were the two examples used by my interviewees to explain their perception that the stability in the work teams was linked to good performance of pharmaceutical assistance. In these cases, the work teams were identified as more committed to the pacts in force because their leaders participated in the negotiation of these instruments. In the words of one of my interviewees, for those leaders, ‘the health of the population is above partisan interests’. My findings concerning political partisan influence in Ceará and Paraná contradict Arretche’s (2000) analysis of the decentralisation of health care in these states. According to Arretche (2000:73), in these two states successive governors of the same political party were responsible for continuity experienced in the policies of health, which in turn resulted in better outcomes. Whereas Arretche associated continuity in health policies with no changes (or continuity) in the governor’s political party, my interviewees suggested that continuity in policies was associated with less political partisan influence, which resulted in low turnover in work teams.

The partisan political alignment of state or municipal leaders with the federal and state level, respectively, was also mentioned as a factor that influenced federative relationships concerning pharmaceutical assistance. Where federal and subnational authorities were from the same political party, policies were usually followed as agreed, while where they were from opposing parties, local authorities used their self-rule power to oppose to national policies. One example of this confrontational approach was provided by one of my interviewees from Sao Paulo: “[b]ecause here

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<sup>154</sup> In Brazil, as a rule of thumb, after elections the executive branch has a significant staff turnover. There is a strong partisan influence in the appointment of state and municipal secretaries and other prominent positions in the structure of the health secretariats.

in São Paulo it was always like this: if the federal government wants this, then the state does not do that”.

Thus, two negative aspects in the development of pharmaceutical assistance were associated with the political party influences: high turnover, which was associated with failure to comply with the covenants that govern decentralisation, and a confrontational approach, resulting in lack of standardisation of services throughout the country. Although my research has investigated only the decentralisation of pharmaceutical assistance, I would suggest that the findings apply to the general decentralisation of health in the Brazilian context. Thus, it is plausible to argue that the negative influence of the high staff turnover in the health secretariat will not be restricted just to pharmaceutical assistance, which is part of the health system.

The data I gathered lead me to identify three conditions, all related to the state level, which are associated with successful initiatives. The first of these conditions is the pre-existing infrastructure and administrative capability within the state. Secondly, there is stability in work teams (as a result of lesser political partisan influence on the appointment of the most important positions in the hierarchy of the secretariat of health). Lastly, there is the engagement of the state health secretariat in the implementation of the decentralisation. The role of the health secretariat is related to the fulfilment of all responsibilities provided in the statutory framework (mainly technical assistance, and coordination), compliance with the pacts and also acting as a 'buffer' absorbing and counterbalancing the deficiencies of the smaller municipalities. State level administration was pointed out as a central piece in the process in situations where the implementation of decentralisation was successful and brought improvements in access to medicines, but also in those examples of failure. Within the accounts of my interviews, however, there are more negative than positive examples, suggesting that the state level is more frequently not playing its expected role according to the legal framework and agreements signed.

The identification of these three conditions helped me understanding how the responsibilities and powers distributed by decentralisation could result in improvements in access to medicines which I highlight as an important finding of my research. At the same time, the accounts of my interviewees suggested that in states where these three conditions were not found, in many cases, public provision of basic medicines worsened when decentralisation was implemented, especially at the beginning of the process.

While this section has highlighted how the state level figures as a major player for the success (and the failure) of decentralisation of pharmaceutical assistance, in the next section I will explore my main findings with relation to the access to medicines after decentralisation.

#### **8.4 Basic pharmaceutical assistance and access to medicines after decentralisation**

As discussed above, decentralisation of pharmaceutical assistance was motivated by problems with access to basic medicines, but did public provision of basic medicines improve with decentralisation?

##### **Pharmaceutical assistance structuring**

When asked, all my interviewees considered that basic pharmaceutical assistance improved as a result of decentralisation. The responsibilities, powers and financial funds transferred were seen by my interviewees as instrumental to the development of the municipal structure devoted to pharmaceutical assistance. To implement the new roles and responsibilities related to the supply of medicines, municipalities needed to develop new administrative capabilities to take on planning, purchasing, storage and dispensing of basic medicines. This improvement in the structure of municipalities dedicated to pharmaceutical assistance resulted, in a certain extent, in better public provision of medicines.

##### **Changes in access that followed decentralisation**

Improvement in access was pointed out as the main strength of the decentralised pharmaceutical assistance. Based on their experience as health secretaries, my interviewees suggested that regularity in provision of basic medicines was an important change that followed decentralisation. In particular, drugs to treat hypertension and diabetes were made available consistently, although it was not the case in all regions of the country.

Despite this perception of improvement in basic pharmaceutical assistance, there are no consistent and reliable systems for monitoring and recording indicators of access to medicines in SUS. Furthermore, as discussed in Chapter Two, studies evaluating access to medicines in Brazil are not comprehensive enough. They only provide a snapshot of the situation rather than a full picture of the situation of public availability of medicines around the country. The lack of indicators and

monitoring system were pointed out, mainly by the Ministry of Health officials I interviewed, as an important barrier to the development of basic pharmaceutical assistance.

Narratives about improvements in regularity and availability of medicines were not consistent. If on the one hand they suggested that shortage was less frequent and access reached broad coverage, on the other hand interviewees agreed that shortages remain in virtually all regions of the country. My interviewees acknowledged that the public provision of medicines fell short of the universal coverage recommended by SUS. This view expressed by my interviewees was corroborated by the Brazilian Auditing Tribunal, which reported poor performance of basic pharmaceutical assistance around the country in 2010, as discussed in Chapter Six.

An unmistakable sign that the availability of medicines remains insufficient to meet the demands of SUS patients is judicialisation. As discussed in Chapter Six, this phenomenon refers to the use of lawsuits against the government (federal, state or municipal level) to obtain prescription drugs not available in SUS pharmacies. While judicialisation started with patients demanding medicines to treat AIDS and cancer, lately it has become more widespread and included even basic medicines. This phenomenon of using the court to seek the fulfilment of the right to medicines provided in the SUS legal framework has reached major proportions in the last ten years. Remarkably, data from my interviews suggested that judicialisation, or rather, a decrease in legal cases requiring medication, was used by health secretaries as a proxy indicator of improvement in access to medicines.

### **Barriers to the progress**

If SUS provision of medicines did not improve as expected after decentralisation, what were the barriers to further progress on access as perceived by my interviewees? A broad range of structural issues already discussed were pointed out, such as regional differences, low management capability (both municipal and state level), insufficient financial resources and absence of tools and indicators for monitoring. Other factors, however, are related to the design and organisation of pharmaceutical assistance policy within the SUS structure, namely, the fragmentation of pharmaceutical assistance and lack of integration between dispensation of medicines and health care.

Considering the decentralised setting and the federative arrangement, what all barriers have in common is that any strategy to solve the problems identified here will necessarily require negotiations in all SUS forums of agreement prior to implementation. As extensively discussed in

Chapter Five, the agreement process entailed is laborious and time consuming. Moreover, considering the autonomy and self-rule power of states and municipalities, implementation will not necessarily be standardised throughout all regions. This scenario led me to conclude that these barriers and difficulties with decentralisation discouraged federal government from strengthening decentralisation and drove it to launch a centralised strategy to deliver basic medicines. In this regard, while SUS subnational actors struggled in implementing decentralisation of basic pharmaceutical assistance, the federal government created, in 2004, an ambitious programme to improve access to basic medicines. The Popular Pharmacy (FP) programme bypassed the main obstacles associated with the federative arrangement. In the next section I will discuss my main findings related to this controversial programme.

### **8.5 Popular pharmacy programme: an alternative way of providing access to medicines**

Taking into consideration the elements I discussed in the previous sections related to access to medicines and the decentralised strategy to manage basic pharmaceutical assistance, it is evident that availability of basic medicines was not sufficient to meet the demands even with the implementation of the NMP. This failure to make basic medicines consistently available for SUS patients helps us to understand, at least in part, how the Popular Pharmacy programme emerged and developed within the decentralised setting. In my interviews, the initiative aroused strong views that showed a clear separation between Ministry of Health officials, who all defend the programme, and my other interviewees, who criticised it.

Especially in Chapter Seven of my thesis, I explored how the Popular Pharmacy programme was created and implemented without significant participation of states and municipalities, and how it impacted on the decentralised setting of basic pharmaceutical assistance. For this discussion it is important to review some key characteristics of this programme. The implementation of the initiative went through three stages. When launched in 2004, it was managed and delivered by the Ministry of Health in public facilities and exclusively employed users' co-payment. In the second stage the programme was expanded using the community pharmacies network. In the third stage drugs to treat diabetes, hypertension and asthma started to be distributed free of charge. It is worth noting that, initially, the Ministry of Health rationale for implementing the FP programme was to provide basic medicines at subsidised prices to Brazilian citizens who, despite having private health plans, could not afford to pay for out-of-pocket medicines because of their low family budget. Thus, at the beginning, the FP was targeted at non-SUS patients.

In my interviews, the feature of user co-payment, applied for the first time in the public health system, proved to be very controversial. On the one hand, this feature differentiated the FP programme from other initiatives of public provision of medicines and, in some way, as the accounts of my interviewees suggested, contributed to the perception of disconnection between the FP programme and SUS, to which I will turn shortly. On the other hand, co-payment was one aspect of the initiative that caused much criticism from municipal and state health secretaries, the National Health Council (the higher instance of SUS), and academia because co-payment was seen as going against the principle of free access to healthcare (which includes medicines), as enshrined in the Brazilian Constitution.

The second stage also generated controversy. In 2006, the federal government expanded the FP programme to incorporate accredited community pharmacies. Underlying this expansion was the undeniable issue of insufficient availability of medicines in SUS pharmacies, as already discussed in Chapter Six. The Ministry of Health's choice to use private partners to improve the coverage of the programme was much criticised because financial resources were being invested in the private sector instead of improving the public sector.

Criticism of users' co-payment was somehow neutralised in the implementation of the third stage of the FP when diabetes and hypertension drugs started to be distributed free. As highlighted in Chapter Seven, according to a Ministry of Health official, these drugs represented 76% of all drugs distributed by the service, and, therefore, a significant proportion of users started to receive free drugs.

Even if the co-payment issue was at least partially solved, the partnership between the federal government and the private sector still causes dissatisfaction. As previously mentioned, state and municipal health secretaries advocated that investments used in the FP should go to SUS, not to the private sector. As a result of that federal priority, the programme has received major financial investments that allowed its rapid expansion throughout the country by using the capillarity of the community pharmacies network.

Although subnational actors disagreed with many points related to the FP programme and had reservations about its implementation strategy, they agreed that the FP improved the availability of medicines. In fact, narratives revealed that as a consequence of better availability of medicines,

consistency in distribution, and the high numbers of community pharmacies, SUS patients are migrating to the FP. This migration was approved and even encouraged by some municipal health secretaries. At first sight this position may seem puzzling, but the accounts of my interviewees suggested that the FP is seen by health secretaries as a means to relieve the pressure for provision of basic medicines. My interviewees also suggested that health secretaries do not see the FP as interference in the decentralised system managed by the municipality by the Ministry of Health, or think of it as recentralisation.

### **Debate about recentralisation was avoided**

Another puzzling question about this programme, which I tried to answer in my research, was how a centralised programme entered the decentralised SUS setting without resulting in major confrontations with subnational actors. My research demonstrated that understanding how the FP programme was created is important in answering this question. Three of my interviewees provided narratives on the influence of the President of the Republic on the creation and expansion of the programme. FP was created during President Lula's rule, and six years later was part of the electoral platform of the following candidate, President Dilma.

The programme, which is clearly identified as a federal initiative,<sup>155</sup> had significant results in the availability of medicines contrasting with the historical shortage faced by municipal public pharmacies. In fact, positive results obtained with the programme, and its potential impact on voters' preference, made even the opposition presidential candidate José Serra<sup>156</sup> to include the FP programme, created by his political adversary, in his electoral platform. Corroborating with this evaluation of the political importance of the FP is the fact that after President Dilma's election, one of her first announcements was the distribution, free of charge, of diabetes and hypertension drugs by the FP programme. The strong commitment of the federal government to the implementation of the initiative, the political power and financial resources given to it are, without doubt, important elements in explaining the role this programme currently plays in the provision of basic medicines.

Another element that contributes to the understanding of the commitment to this programme is related to the private sector partnership and its contributions to the improvement in access to medicines. My interviews with Ministry of Health officials suggested that the federal government

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<sup>155</sup> It is compulsory the exhibition of a standard banner in the community pharmacies accredited in the FP programme, which should contain the logos of the Ministry of Health and federal government. Moreover, television adverts also portrays FP as a federal government initiative.

<sup>156</sup> José Serra was defeated by Dilma Rouseff in the second round of the 2010 presidential elections.

found in the private sector the solution to overcome the barriers for the development of the basic pharmaceutical assistance. Private sector assets, such as the widespread network of pharmacies, human resources, administrative capability, and consistent availability of medicines ready to be dispensed, were employed to solve historical failures experienced in SUS pharmaceutical assistance services. Moreover, another characteristic of the private partnership relates to funding. Community pharmacies receive payment for the drugs distributed directly from the federal government. Unlike in SUS, where the decentralised model entails co-funding by the three tiers, in this case, there was no counterpart contribution or negotiations in agreement forums. As highlighted in Chapter Six, in the view of one Ministry of Health official, partnership with the private sector avoided lengthy negotiations and dependence on the fulfilment of agreements. Moreover, as no counterpart contributions were involved, it simplified the overall process.

In sum, the FP programme introduced a new strong actor (the private sector) and new mechanisms (co-payment and private facilities) to the process of public provision of basic medicines. The initiative was implemented without effective participation of state and municipal health secretaries in the design and implementation. Remarkably, both the exclusion of these actors, and the whole approach taken by the federal government run contrary to the decentralisation strategies that have been built up over the years in pharmaceutical assistance. As I discussed in Chapter Five, my interviewees pointed out the importance of the forums of agreement and the processes of negotiation introduced by decentralisation. Therefore it is plausible to ask why the excluded subnational actors did not confront the Ministry of Health decision to launch a programme in partnership with the private sector to distribute the same drugs that SUS should distribute. Based on my interviews, I argue that the federal government succeeded in avoiding major opposition by using at least three strategies. Firstly, the federal level did not change the legal framework regarding the responsibilities of subnational actors. Secondly, as discussed in Chapter Seven, the Ministry of Health used separate financial resources to fund the FP and SUS pharmaceutical assistance.<sup>157</sup> And lastly, the federal level evoked the ‘right to health’ (and medicines) constitutional principle to justify the programme. No pro-decentralisation discourse could contradict this argument.

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<sup>157</sup> As discussed in Chapter Seven, the federal government states that it does not decrease the transfer of federal funds for SUS basic pharmaceutical assistance. In 2013, however, the federal government allocated R\$2 billion to the FP, while R\$1.23 billion were allocated to SUS basic pharmaceutical assistance.

## **8.6 Contributions to existing scholarship**

This thesis has three main contributions to scholarship, particularly in the fields of decentralisation, fiscal federalism, and policy research. My research offers new insights in the study of decentralisation policies by raising awareness of how, seemingly paradoxically, decentralisation can enable (re)centralisation. My work also shows that political gains (such as electoral gains) can motivate national government to double fund the provision of health services, opposing the expected transferring of responsibility for expending to subnational actors. The work also evidenced that the limitations and difficulties inherent to federative relationships involved in the implementation of a decentralised policy can be used to justify partnerships with the private sector, and (re)centralisation.

### **8.6.1 Contribution to decentralisation research**

One way in which this thesis has contributed to advance decentralisation research is through its focus on exploring the interplay between centralised and decentralised modes of implementation. By offering an explanation on how federal government can divert attention from centralisation, my thesis adds to the Exworthy *et al.*'s (2010:8) work who found that policy attention on decentralisation can mask the opposite, namely that centralisation is taking place.

In the case of Brazil, decentralisation in itself and the complexity of intergovernmental relationships involved were important elements that facilitated the implementation of the FP programme, a centralised initiative to provide medicines. As a result, the federal government has implemented, in parallel, a centralised programme to perform the same activities that were being devolved to states and municipalities, thereby taking advantage of the weaknesses and difficulties experienced by subnational actors in the decentralisation process. Another circumstance that, in the Brazilian case, contributed to the masking of (re)centralisation was the unquestionable commitment of SUS and its leaders to decentralisation. In the views of subnational actors (as indicated by my interviewees) decentralisation was unchangeable for having been enshrined in the constitution.

As highlighted in Chapter seven, unlike in Europe (especially in Nordic countries), that has had a tradition of decentralised governance, and in the 2000s had important health functions recentralised, in Brazil (re)centralisation and decentralisation of basic pharmaceutical assistance occurred concomitantly. The awareness of differences in approach to policy implementation are of interest to those studying health reforms and offers an opportunity to compare the strategies to recentralise the provision of medicines conducted in Brazil and the recentralisation of health

services recently implemented in Europe. Those differences could contribute to the on-going debate on recentralisation of health care in European countries.

### **8.6.2 Contribution to studies on fiscal federalism**

My findings challenge the understanding reached by scholars of decentralization in the tradition of the theory of fiscal federalism, who state that the federal government seeks, first and foremost, to get rid of the responsibility for spending. Considering this tradition, in a decentralised environment, Garman *et al.* (2001) argue that we would expect federal government to be more inclined to transfer responsibilities than the resources to meet them.

In the case of pharmaceutical services in Brazil, as discussed in Chapter seven, the federal government doubled the funding for the provision of basic medicines after decentralisation. At the same time that the federal level kept the transfer of funds to municipalities to co-finance the decentralised provision of basic medicines, they funded the FP programme. In this circumstance, the political gains provided by a centralised programme led to the subversion of the economic logic advocated by the theory of fiscal federalism. Thus, it is plausible to infer that, in the name of political gains, national governments can decide not to transfer expenditure responsibilities to local governments, and scholars should examine this aspect when studying decentralisation policies.

### **8.6.3 Contribution to policy research**

My thesis contributes to advance policy research by exploring intergovernmental relationships related to pharmaceutical assistance, offering a new view on the implementation of a contested policy. My work shows that the federal government used the 'limitations' or 'difficulties' inherent to the Brazilian federal arrangement (as for example, the autonomy of states and municipalities and the lengthy negotiations preceding the implementation of policies) to justify the implementation of a centralised initiative, the FP programme, producing significant political gains.

As discussed in Chapter seven, with regards to the provision of medicines, states and municipal levels are interdependent and the distribution of medicines is based on intertwined actions performed by both tiers. The strategy used by the federal government to introduce the FP took advantage of this interdependence between states and municipalities. Besides the inherent contradictions with the principles of decentralisation of the SUS, the federal government managed to construct the FP to be acceptable and even attractive to both levels.

The circumstances that allowed decentralisation and centralisation to happen concomitantly is also important to explain the success of the federal government in implementing the FP. The difficulties experienced by state and municipal secretaries in the course of implementation of the decentralisation dominated the agenda of discussion on SUS, diverting the attention from FP and, in a certain extent; FP had time to be consolidate and to improve availability of medicines. The satisfactory performance of FP resulted in a positive feedback and, at the same time, the programme has gained increasing importance in the scenario of public provision of medicines. The federal government transformed a “quicksand” policy – the provision of drugs within a complex federative arrangement – into an initiative planted in a fertile and firm ground for the proliferation of political dividends. This success was possible because the federal level managed to avoid major confrontation with subnational actors (see Chapter seven) in the conduction of FP’s implementation. My findings indicate that policy scholars should be aware that national governments’ ingenious approaches to enable policy implementation may even contradict the legal framework if this results in political gains.

## **8.7 Limitations of the study**

My study has a number of limitations. Amongst these were the constraints on time and funds that prevented me from conducting more interviews.<sup>158</sup> I conducted the interviews in Brazil over a short period of time, so it was difficult to arrange all interviews in that time-span, and in two cases I could not wait for interviews which had been cancelled to be rescheduled before I had to leave the country to return to the UK. Although I planned to interview most of the participants in Brasilia, where the important SUS forums and most Ministry of Health officials are based, there were some potential informants from other regions of the country that I could not interview because I did not have the funds or time to travel to their locations. Another aspect of having a short time-span to conduct the interviews relates to the impossibility of transcribing the interviews immediately, as I intended in the first place. In order to minimise the inconvenience of missing some of the thoughts and impressions I tape-recorded my perceptions or any other information immediately after each interview when possible.

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<sup>158</sup> I was living in the UK but travelled to Brazil to conduct the interviews in 2011, during the second year of my PhD. This was an expensive trip and I could not afford to return for more interviews. Moreover, I had a leave period of three years from my employer to complete my PhD.

Personal bias is an important methodological limitation inherent to elite interviews, and to minimise its effects on my analysis I used multiple sources and checked some interviewees' claims in policy documents when possible. It was especially useful in those cases where it was difficult for me to distinguish in interviewees' accounts what was actually implemented from what remained as a plan or policy goal. The chronology of certain steps of the decentralisation process was not clear in certain accounts, so I cross-checked these with other sources. As noted by Berry (2002:680), "[i]nterviewers must always keep in mind that it is not the obligation of a subject to be objective and to tell us the truth." In my work it was important to be aware of this inevitable lack of objectivity in my participants.

Although I managed to include the three tiers of the government quite successfully – I interviewed health secretaries from different regions of the country and key informants in the Ministry of Health – this research would also have profited from the views of users or patients. Through such interviews I would explore the perspectives of representatives of patients' associations, for example diabetes and hypertension associations from each region of the country. In my work I focused on the views of those SUS actors involved in policy-making and implementation. Patients' perceptions and experiences would certainly provide fresher and different insights about access to basic medicines in Brazil. Although this approach could bring new perspectives, and compensate for some of the limitations of my study, I consider this an opportunity for further research, which I will develop in the next section.

## **8.8 Suggestions for future research**

The investigation of what agreement of pharmaceutical assistance policy in CIT means for each of the three levels of the federation is another point of great interest which I would like to investigate. As we are reminded by Walt (1994:73), power relations are at the core of every health policy process. The role of the government bodies involved in policy-making and policy-decisions, and the power shared in federative states, are also important elements in this equation. In my work I investigated, to some extent, the interplay between the tiers of government regarding the negotiations to decentralise and implement pharmaceutical assistance policy. In fact, the process of agreement was very much valued, and frequently highlighted by my interviewees, but it was not possible to further explore what this meant to each of the actors involved. Therefore, to explore what is actually agreed in SUS forums and how this process occurs would be of value in advancing the debate about power relations in health policy-making. In such future research, in addition to

interviews, I would systematically use observation of CIT and CIB meetings, the proceedings of CONASS and CONASEMS meetings, and the minutes generated in these meetings.

With regards to the FP programme, the investigation of the impact of this initiative in states and municipalities where SUS pharmaceutical assistance was successful would be very useful to conclude if the FP is competing with SUS for patients, or if the FP is only filling in the deficiencies in medicine provision that SUS was unable to solve. With respect to this particular field, a case study with the Paraná Consortium of Medicines and the role of the FP programme in that state would certainly offer a new perspective for decentralisation studies in Brazil.

## **8.9 Concluding remarks**

As these discussions have indicated, the decentralisation of pharmaceutical assistance in Brazil and its impact on access is a complex subject. My interviewees' assessments and experiences of how the process was conducted and its outcomes are ambivalent and sometimes contradictory. Overall, decentralisation was seen as an important step to improve the organisation of pharmaceutical assistance and the access to basic medicines. The expected improvement in access, however, was not achieved evenly around the country. Decentralisation in itself was not sufficient for improving access (or service standards) in less developed regions. Moreover, decentralisation of pharmaceutical assistance was associated with increased inequalities, contributing to deepening the existing regional differences in health delivery. SUS forums of agreement are seen as very important in the policy process for subnational actors, whereas their proceedings are seen as laborious and time-consuming by Ministry of Health officials. Regarding the agreements between the three tiers of government to manage pharmaceutical assistance, the lack of compliance with the pacts by the state level was pointed out as one of the main barriers to improving access to medicines. In this context of struggle to improve access, the implementation of the FP programme controlled by the federal government (and delivered by community pharmacies) aroused contradictory assessments. The programme has achieved high coverage and consistent availability of basic medicines in a short time-span. Municipal health secretaries criticised federal investment in the programme, but they acknowledge that FP decreases the demand for drugs in SUS, relieving the burden on the municipality. Although it is centrally controlled, the federal government managed to avoid major opposition from subnational actors to this centralised programme by portraying it as an initiative that does not interfere in the decentralised setting of pharmaceutical assistance.

My findings suggest that there is no clear indication of whether decentralisation or centralisation is the best alternative for improving access to basic medicines in Brazil. Both approaches worked well in some contexts but failed in others. I believe that the theme and findings of my research will be useful for other scholars and policy-makers interested in decentralisation. With this thesis I offer a panorama of the policies, relationships and issues involved in Brazilian pharmaceutical assistance for provision of basic medicines, which researchers could draw on for further investigations.

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## APPENDIXES

### APPENDIX 1

#### TIMELINE OF THE LEGAL FRAMEWORK RELATED TO BASIC PHARMACEUTICAL ASSISTANCE IN BRAZIL

**1971** Creation of the Central of Medicines (CEME – *Central de Medicamentos*)

**1987** The CEME launches the Basic Pharmacy an initiative to distribute to municipalities 48 drugs within RENAME list to meet the needs of 3,000 inhabitants for a period of six months.

**1997** CEME was extinct.

Health Ministry establishes Basic Pharmacy Programme (PFB) based on similar assumptions to those of CEME basic pharmacy (i.e. drug sets to serve about 3,000 inhabitants in cities with up to 21,000 inhabitants). Medicines, acquired by Ministry of Health, were sent to distribution poles located in each region of the country. Subsequently, the PFB was reformulated, excluding the states from participating, as opposed to the emerging process of decentralisation/organisation in progress in various units of the federation regarding pharmaceutical assistance.

**1998** Launching of National Medicines Policy (NMP). Main changes are related to decentralisation of pharmaceutical assistance management, promotion of rational drug use, effectiveness of distribution in the public sector, and initiatives to reduce the prices of medicines including out-of-pocket.

**1999** Ministry of Health Order 176 established specific financial incentives for Basic Pharmaceutical Assistance – IAFB,<sup>159</sup> as well as criteria and requirements for qualification of

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<sup>159</sup> IAFB-Incentive to Basic Pharmaceutical Assistance was a special source of funding established by the Ministry of Health in 1999. The funds to finance the purchase of medicines are: 50% from the federal government, 25% from states, and 25% from municipalities. The total value proposed by Ministry of Health approved by the Tripartite Intergovernmental Commission (CIT) was R\$ 2.00 (approximately 70p) per inhabitant/year (federal contribution: R\$ 1.00 per inhabitant/year and state and municipal level contribution of at least R\$ 0.50 per capita/year each).

Federal funds are transferred by the National Health Fund to the respective state and local health funds, in monthly instalments in proportion to the number of inhabitants of the municipalities.

As a condition to access the IAFB states have to develop the State Plan of Basic Pharmaceutical Assistance to be updated and approved annually by the Bipartite Intergovernmental Commission (CIB). This Plan should include: i) a list of basic medicines for Pharmaceutical Care to be purchased with this resource, ii) the

municipalities and responsibilities agreed between the three management levels of SUS. The IAFB unlike the Basic Pharmacy Programme (PFB – *Programa Farmácia Básica*), included all the municipalities independent of the number of inhabitants. The ordinance also provided for the participation of state and municipal managers in the financing and management processes. This was considered the first step towards effective decentralisation of the pharmaceutical assistance in Primary Care.

**2001** Initiatives for centralised acquisition of basic medicines. Despite the process of decentralisation the Ministry of Health started to acquire and distribute a set of drugs designed to support strategies and activities of basic care, including the Family Health Programme (PSF). Some of the drugs contained in the set overlapped those financed by the IAFB as for example the diabetes and hypertension drugs. Moreover, Ministry of Health officials dealt directly with PSF teams of municipal health secretaries excluding the participation of the state level in this initiative.

**2002** Medicines to treat diabetes and hypertension were purchased by the Ministry of Health and distributed directly to municipalities.

**2003-** First year of Lula's presidency. This year was marked by changes in the structure of the Ministry of Health departments. It was also the beginning of negotiations between CONASS (National Council of State Health Secretaries) and the Ministry of Health about Basic Pharmaceutical Assistance decentralisation policies.

**2004** - In May 2004, National Health Council (CNS) approved the National Policy for Pharmaceutical Assistance (PNAF). Decentralization of basic pharmaceutical assistance was set up as the strategic priority of this policy.

**2004** - In June, the Ministry of Health launched the Popular Pharmacy Programme, to improve the availability of essential medicines. The programme introduced the users' co-payment. Users pay 10% of the costs out-of-pocket, and the government subsidises up to 90%. The programme was coordinated and executed by the Ministry of Health and the (public) Oswaldo Cruz Foundation (FIOCRUZ) through public pharmacies (SUS-'owned' pharmacies) dedicated to the programme.

**2005** - In July, the Ministry of Health regulated the Basic Pharmaceutical Assistance, increased the minimum value of IAFB, and started the transfer of funds to municipalities and states for the

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adhesion mechanisms and a degree of accountability of the municipalities; iii) the covenant of resource management, with the establishment of values for state and local contributions, and iv) the systematic programming, monitoring and evaluation of its implementation in the state.

The Ministry of Health set the minimum list of drugs to be acquired by Incentive Basic Pharmaceutical Assistance.

purchasing of some basic drugs. The purchase of medicines for diabetes and hypertension remained centralised under the Ministry of Health.

**2005-** Negotiations between the Ministry of Health, states and municipalities regarding the Basic Pharmaceutical Assistance led to the definition of two groups of medicines related to primary care:

-Strategic (set of drugs whose responsibility for acquisition and/or financing was of the Ministry of Health): hypertension and diabetes, including insulin, asthma and rhinitis, women's health, nutrition, and tobacco control.

-Decentralised (funded by the IAFB with contributions from the Ministry of Health, states and municipalities): According to CIB and CIT agreements in, purchasing would be states or municipalities' responsibility.

**2006** – A ministerial ordinance established that the decentralisation of financial resources for the acquisition of medicines to treat diabetes and hypertension depended on agreements in CIT and later in CIB forums.

**2006- *Pacto pela Saude***- 'Pact for Health' was approved by the CIT in January 2006. The pact is an agreement in which managers at every level of government were committed to complying with health objectives and responsibilities. The Pact aimed to establish joint responsibility in SUS more clearly, in which all managers were considered to be invested with full responsibilities, replacing the former accreditation process with a new system where they should observe the Statement of Commitment and Management (TCG). The TCG has goals and objectives of the Pact for Health, duties and responsibilities of each manager and corresponding monitoring indicators. Another important element introduced by the Pact concerned the financial resources that changed from monthly payments linked to the service delivered, to 'block funding' corresponding to a certain amount of money to finance the services required to reach the targets agreed in the TCG. Financial incentives for the development of management and planning capabilities were also provided under this new scheme of funding.

**2006-** The Popular Pharmacy Programme was extended to the community pharmacies network. This expansion was called *Aqui Tem Farmácia Popular* ('There is a Popular Pharmacy Here'). At this stage existing community pharmacies entered into a contract with the Ministry of Health. This second stage of the programme was implemented rapidly, and participating community pharmacies grew from 2,955 in 2006 to 20,225 in 2011.

**2011** - The third stage of the Popular Pharmacy programme was implemented with the initiative *Saude Não Tem Preço* ('Health is Priceless'). This stage started the distribution, free of charge, of drugs to treat diabetes and hypertension in 'owned' and community pharmacies. In addition to

these free medicines, FP is still dispensing drugs in the co-payment scheme for the treatment of cholesterol, osteoporosis, Parkinson's disease, glaucoma, rhinitis and dyslipidemia, as well as providing contraceptives and geriatric diapers. Currently, the FP programme offers 25 items, of which 14 are distributed free of charge and the other nine being sold with a discount of up to 90%.

**2012-** The distribution, free of charge, of medicines to treat asthma was introduced by the Popular Pharmacy programme.

**Appendix 2- Description of studies measuring medicines access in Brazil (1998 to 2009).**

Reference	Scope/year of data collection	Study Design	Studied sample	Evaluated Medicine	Study focus	% general availability	% public availability (SUS facilities)	% out-of-pocket availability	% prescribed drugs dispensed
<b>National Studies</b>									
Cosendey 2000	National; Multi-centre study in 5 states (AC,AM,GO,PE and RJ) to evaluate the implementation of <i>Farmácia Basica</i> programme 1999	Multiple case study	Public Health Units in 12 municipalities in 5 states; 75 informants involved in the management of the programme (5 from national level, 4 regional and 66 at the municipal level;  116 health service patients	Standard set of 40 essential medicines distributed by the PFB <sup>1</sup>	Public Health Units	General availability of the FBP drugs according to WHO definition	52.81%	-	83.46%  The goal according to WHO is 95%
Karnikowisk 2004	National; 11 Metropolitan areas distributed in the 5 geographical regions of Brazil  2002	Cross-sectional in primary care health units; instrument developed by the authors	Public Health service patients; 50 Public Health Units	61 drugs distributed over 13 of the 19 pharmacological groups comprise on the RENAME <sup>2</sup>	Public Health Units		55.4%		

Reference	Scope/year of data collection	Study Design	Studied sample	Evaluated Medicine	Study focus	% general availability	% public availability (SUS facilities)	% out-of-pocket availability	% prescribed drugs dispensed
Carvalho 2005	National 2003	Medicine utilization.  Cross-sectional study based on survey designed by the WHO to evaluate health systems performance of the member countries (adapted to Brazil)	Population based study:  5000 adults, 18 years or older, 5 thousand households, 250 census tracts, 188 cities, 25 estates	11 groups of medicines	Household survey				87% had succeeded in obtaining all medication prescribed.  Within the 13% of patients that failed in obtaining their medication, 55% of them alleged lack of money.
Emmerick 2009 OPAS 2005	Multi-centre study in 5 states (ES,GO,PA,RS,SE) 2004	Descriptive cross sectional study based on survey designed by WHO about medicines access/use (adapted for Brazil)	Households, of all ages, acute illness in the last two weeks, in 916 houses, five states, two cities in each state	RENAME and set of standard drugs distributed by PFB	Household survey		73%		65.7%  Average time of supply shortage of medicines in SUS facilities was 84.1 days.

Reference	Scope/year of data collection	Study Design	Studied sample	Evaluated Medicine	Study focus	% general availability	% public availability (SUS facilities)	% out-of-pocket availability	% prescribed drugs dispensed
Pinto 2010	National; 30 cities 2007	Methodology developed by the WHO in partnership with the Health Action International, to compare medicines prices and a availability	FP – Popular Pharmacy Programme in public ('owned') and community pharmacies	Four selected drugs for hypertension and diabetes treatment	Public and community pharmacies in the Popular Pharmacy Programme		Diabetes 23.3%  Hypertension 86.7%	Diabetes 100%  Hypertension 100%	
Paniz 2008	Regional 41 cities in South and Northeast Brazil 2005	Cross-sectional study, instrument developed by the researchers	The sample included 4,060 adults (30 to 64years old) and 4,003 elderly (65+) living in areas covered by primary health care clinics.	Medicines to treat diabetes, hypertension and mental health conditions	Household survey	Adults 81.2%  Elderly 87%  Measured as access to all medicine needed last month			

Reference	Scope/year of data collection	Study Design	Studied sample	Evaluated Medicine	Study focus	% general availability	% public availability (SUS facilities)	% out-of-pocket availability	% prescribed drugs dispensed
<b>Northern Region Studies</b>									
Emmerick 2009 OPAS 2005	Multi-centre study in 5 states (ES,GO,PA,RS,SE) 2004	Descriptive cross sectional study based on survey designed by WHO for households survey about medicines access/use (adapted for Brazil)	Households, of all ages, acute illness in the last two weeks, in 916 houses, five states, two cities each state	Medicines for acute conditions	Household survey		65.7%		69.5%
Cosendey 2000	National; Multi-centre study in 5 states (AC, AM, GO, PE and RJ) to evaluate the implementation of <i>Programa Farmácia Básica</i> (PFB) <sup>1</sup> 1999	Multiple case study	Public Health Units in 12 municipalities among the 5 states; 116 health service patients	Set of 40 essential medicines distributed by the PFB	Public Health Units				AC 63.37% AM 82.73%

Reference	Scope/year of data collection	Study Design	Studied sample	Evaluated Medicine	Study focus	% general availability	% public availability (SUS facilities)	% out-of-pocket availability	% prescribed drugs dispensed
<b>Northeastern Region Studies</b>									
Cosendey 2000	National; Multi-centre study in 5 states (AC, AM, GO, PE and RJ) to evaluate the implementation of <i>Programa Farmácia Básica</i> 1999	Multiple case study	Public Health Units in 12 municipalities among the 5 states; 116 health service patients	Set of 40 essential medicines distributed by the PFB	Public Basic Health Units (UBS)		GO 78%  (% of medicines available in the UBS)		PE 95.68  GO 100%  RJ 83.9%
Emmerick 2009  OPAS 2005	Multi-centre study in 5 states (ES, GO, PA, RS and SE) 2004  PA state	Descriptive cross sectional study based on survey designed by WHO to evaluate medicines access/use (adapted for Brazil)	Households, of all ages, acute illness in the last two weeks, in 916 houses, five states, two cities each state	For acute conditions	Household survey	SE 75.5%			SE 54.9%  GO 74%

Reference	Scope/year of data collection	Study Design	Studied sample	Evaluated Medicine	Study focus	% general availability	% public availability (SUS facilities)	% out-of-pocket availability	% prescribed drugs dispensed
<b>Midwestern Region Studies</b>									
Cunha 2002	Municipal; Campo Grande-MS 1999	Cross sectional study based on medicine indicators designed by WHO	12 Public Health Units ; 713 patients interviewed	40 essential drugs	Public Health Units	87.2%			80.7%
Naves 2005	Regional; Distrito Federal 2001	Cross sectional study based on medicine indicators designed by WHO	15 Public Health Units;	40 essential drugs	Public Health Units	83.2%			61.2%
Siqueira 2009	Regional; Distrito Federal 2006	Cross sectional study based on medicine indicators designed by WHO adapted by the researchers	Board of Pharmaceutical Assistance of Distrito Federal; 2 pharmaceutical supply centres; 66 pharmacies or dispensaries; 1330 users interviewed (20 per pharmacy)	50 index drugs according to WHO guidelines	Public Health Units		79.9%		63%

Reference	Scope/year of data collection	Study Design	Studied sample	Evaluated Medicine	Study focus	% general availability	% public availability (SUS facilities)	% out-of-pocket availability	% prescribed drugs dispensed
<b>Southwestern Region Studies</b>									
Santos 2004	Municipal; Ribeirão Preto-SP 1998	Cross sectional study based on medicine indicators designed by WHO	10 Public Health Units	All medicines the UBS was suppose to dispense according to REMUME <sup>4</sup>	Public Health Units				60.3%
Chaves 2005	Municipal, RJ 2002	Case study based on medicine indicators designed by WHO, adapted to Brazil	01 Public Health Unit	All medicines the UBS was suppose to dispense according to REMUME	Public Health Units				65.3%
Guerra 2004	Regional, MG 2000 to 2001	Survey	69 Health Units	21 index essential drugs within the PFB	Public and Private Health Units and pharmacies	81.2% in private pharmacies	46.9%		

Reference	Scope/year of data collection	Study Design	Studied sample	Evaluated Medicine	Study focus	% general availability	% public availability (SUS facilities)	% out-of-pocket availability	% prescribed drugs dispensed
<b>Southern Region Studies</b>									
Marcondes 2002	Municipal, Ponta Grossa, Parana State 2001	Descriptive study based on medicine indicators designed by WHO, adapted to Brazil	20 Public Health Units	All medicines the Unit was suppose to dispense according to REMUME	Public Health Units				73%
Bertoldi <i>et al.</i> 2009	Municipal, Pelotas, Rio Grande do Sul State 2003	Cross sectional study, survey, instrument developed by the researchers	900 households, 2988 individuals of all ages, living in an area covered by assisted by the <i>Saúde da Família</i> <sup>3</sup> programme	All medicines the programme was suppose to dispense according to REMUME	Household survey	96.4%	51%	41.5%	

Reference	Scope/year of data collection	Study Design	Studied sample	Evaluated Medicine	Study focus	% general availability	% public availability (SUS facilities)	% out-of-pocket availability	% prescribed drugs dispensed
Mendis 2007	Multi-centre, 3 low–middle income countries (Brazil, only in Rio Grande do Sul state; Pakistan and Sri Lanka) and 3 low-income countries (Bangladesh, Malawi and Nepal) 2005	Cross-sectional study, survey on medicine indicators adapted from WHO–Health Action International manual	20 Public Health Units and 20 private outlets (Brazil)	32 medicines used to treat cardiovascular disease, diabetes, chronic respiratory disease, glaucoma and to provide palliative cancer care	Public and Private Health Units and pharmacies		30%		
Dal Pizzol 2010	8 municipalities in 3 states : Rio Grande do Sul, Santa Catarina e Mato Grosso do Sul 2006-2008	Multi-centre, longitudinal study, 24 patients per month in each Health Unit participated on a survey, instrument developed by the researchers	8 Public Health Units	All medicines prescribed in the Health Units investigated	Public Health Units		76.1% of all medicines prescribed 88.1% if only essential medicines prescribed were considered		

Reference	Scope/year of data collection	Study Design	Studied sample	Evaluated Medicine	Study focus	% general availability	% public availability (SUS facilities)	% out-of-pocket availability	% prescribed drugs dispensed
Bertoldi 2010	6 cities ( the capital plus 5 others) within the Rio Grande do Sul State  2008-2009	Cross-sectional study, survey on medicine indicators WHO methodology	56 public and private pharmacies	50 medicines : 29 were part of the WHO/HAI global and regional core lists, whereas the remainder list, were selected from the national (RENAME) and municipal (REMUME) lists of essential medicines	Public and Private Health Units and pharmacies		69%  90% in Popular Pharmacy Programme		

<sup>1</sup> PFB- Basic Pharmacy Programme

<sup>2</sup> RENAME- National Essential Medicines List

<sup>3</sup> 'Health of the family' programme

<sup>4</sup> REMUME - Municipal List of Essential Medicines

## APPENDIX 3

### INTERVIEW GUIDES

#### Topics/questions

#### Set A- Municipal Health Secretaries members of the CONASEMS

1. What do you understand by the terms “decentralisation” and “recentralisation” in the context of basic pharmaceutical assistance in Brazil?
2. Do you have any thoughts on the extent of pharmaceutical assistance decentralisation in recent years? What has changed?
3. In your view, why was pharmaceutical assistance decentralised?
4. Who, in your view, had supported or advocated decentralisation of basic pharmaceutical assistance?
5. Was there anyone against decentralising pharmaceutical assistance?
6. Who do you think has benefited the most from decentralisation of pharmaceutical assistance?
7. According to your experience, what is the strength of the pharmaceutical assistance policy, especially regarding essential drugs? And the main weakness?
8. What is the main issue/barrier regarding the access to essential drugs?
9. Tell me about municipality autonomy to manage pharmaceutical assistance of essential drugs. How about state autonomy?
10. How about the access to diabetes type 2 and hypertension drugs: what has changed with the decentralisation?
11. Tell me about the influence/impact of the Popular Pharmacy Programme on the dynamics of delivery of diabetes type 2 and hypertension drugs by municipalities. No changes, synergism, competition with the private sector, or what else.
12. Tell me about the municipalities’ participation on the policy-making process of the Popular Pharmacy Programme?
13. What is the main issue regarding the access to essential drugs experienced by municipalities?

14. Tell me about the role of the states regarding essential drugs. Someone could play the same role or substitute actions of this government tier? Is the role of the state essential for municipalities? How about the federal level? Could its role be possibly transferred to other level?
15. Do you have an example of municipal initiative or demand that resulted in changes in policies? And how about demands that did not succeed.
16. In your opinion, what is the main achievement of decentralisation of pharmaceutical assistance? Which positive results in this area could you assign as a result or consequence of decentralisation?
17. The government has been emphasizing in the media and conferences, about the savings that is obtained with the purchase of medicines because of economies of scale achieved by centralised purchasing. This practice was evident during the Cardoso government with the Ministry Jose Serra and has been repeated since then. What CONASEMS thinks about it? Is the subject discussed by health secretaries? How does it affect the municipal/state autonomy to manage basic pharmaceutical assistance?
18. In your opinion, what could explain the lack of integration between pharmaceutical assistance and the changes that were occurring in health care, especially in relation to decentralisation since the implementation of SUS?
19. The government, in 2005, at the same time that regulated the decentralisation of resources to purchase medicines for the treatment of diabetes 2 and hypertension has expanded the Popular Pharmacy programme to include the community network on the distribution of these drugs. In your opinion, what was the justification for adopting policies that could be regarded as contradictory, i.e., centralised and decentralised programmes to distribute the same drugs?

*Characteristics of respondents*

Age:

Gender:

Job title:

Length of time in job:

Job specific qualification:

**Set B-** State Health Secretaries members of CONASS

1. What do you understand by the terms “decentralisation” and “recentralisation” in the context of basic pharmaceutical assistance in Brazil?
2. Do you have any thoughts on the extent of pharmaceutical assistance decentralisation in recent years? What has changed?
3. In your view, why was pharmaceutical assistance decentralised?
4. Who, in your view, had supported or advocated decentralisation of basic pharmaceutical assistance?
5. Was there anyone against decentralising pharmaceutical assistance?
6. Who do you think has benefited the most from decentralisation of pharmaceutical assistance?
7. According to your experience, what is the strength of the pharmaceutical assistance policy, especially regarding essential drugs? And the main weakness?
8. Tell me about the State autonomy to manage the pharmaceutical assistance of essential drugs. How about municipal autonomy?
9. How about the access to diabetes type 2 and hypertension drugs: what has changed with the decentralisation?
10. Tell me about the influence/impact of the Popular Pharmacy programme on the dynamics of pharmaceutical assistance in municipalities (especially the delivery of diabetes type 2 and hypertension drugs). Where there no changes, synergism, competition with the private sector, or what else did occur?
11. Tell me about the states’ participation on the policy-making process of the Popular Pharmacy programme?
12. What is the main issue regarding the access to essential drugs experienced by the states?
13. Tell me about the role of the states regarding essential drugs. Someone could play the same role or substitute actions of this government tier? Is the role of the state essential for municipalities? How about the federal level? Could the federal role be possibly transferred to the states?
14. Do you have examples of state initiatives or solutions that resulted in changes in pharmaceutical assistance policy? And how about demands that did not succeed?

15. In your opinion, what is the main achievement of decentralisation of pharmaceutical assistance? Which positive results in this area could you think are a result (or consequence) of decentralisation?
16. The government has been emphasizing in the media and conferences, about the savings that is obtained with the purchase of medicines because of the economy of scale achieved with centralised purchasing. This practice was evident during the Cardoso government with the Ministry Jose Serra and has been repeated since then. What CONASS think about it? Is the subject discussed by health secretaries? How does it affect the state autonomy?
17. In your opinion, what could explain the lack of integration between pharmaceutical assistance and the changes that were occurring in health care, especially in relation to decentralisation since the implementation of SUS?
18. The government, in 2005, at the same time that transferred funds to state and municipalities to purchase basic medicines (especially those to treat diabetes 2 and hypertension) the federal government has expanded the Popular Pharmacy programme to include the private network on the distribution of these drugs. In your opinion, what was the justification for adopting policies that could be regarded as contradictory, i.e., centralised and decentralised programmes to distribute the same drugs?
19. The CONASS advocates the need for overcoming the fragmentation of pharmaceutical assistance. How would this be achieved? Who supports this idea? Who opposes?

*Characteristics of respondents*

Age:

Gender:

Job title:

Length of time in job:

Job specific qualification:

### Set C-Ministry of Health Officials

1. What do you understand by the terms “decentralisation” and “recentralisation” in the context of basic pharmaceutical assistance in Brazil?
2. Do you have any thoughts on the extent of pharmaceutical assistance decentralisation in recent years? What has changed?
3. In your view, why was pharmaceutical assistance decentralised?
4. Who, in your view, had supported or advocated decentralisation of basic pharmaceutical assistance?
5. Was there anyone against decentralising pharmaceutical assistance?
6. Who do you think has benefited the most from decentralisation of pharmaceutical assistance?
7. According to your experience, what is the strength of the pharmaceutical assistance policy, especially regarding essential drugs? And the main weakness?
8. What is the main issue/barrier regarding access to essential drugs?
9. Tell me about municipalities’ autonomy to manage pharmaceutical assistance of essential drugs. How about state autonomy?
10. The management of essential drugs, especially diabetes type 2 and hypertension is made by both, decentralised and centralised programmes. What was the rationale for having different strategies for the same drugs?
11. In your opinion, what could explain the lack of integration between pharmaceutical assistance and the changes that were occurring in health care, especially in relation to decentralisation since the implementation of SUS?
12. Tell me about the different programmes and how they affect the pharmaceutical assistance. What is the justification for keeping distinct programmes and separate sources of funding for the supply of the same drugs, as for example diabetes and hypertension?
13. Much has been said that pharmaceutical assistance is still focused on the purchasing and distributing medicines. Who or what is it to blame for [the poor outcomes]?
14. The Popular Pharmacy programme was, firstly, focused on those patients that did not use SUS, but that did not have sufficient income to afford to buy the prescribed medicines. What has changed [in the programme] and why?

*Characteristics of respondents*

Age:

Gender:

Job title:

Length of time in job:

Job specific qualification:

## APPENDIX 4

### ACRONYMS

AFB	Assistencia Farmacêutica Básica – Basic Pharmaceutical Assistance
CEME	Central de Medicamentos – Central of Medicines
CGU	Controladoria Geral da República - Office of the Comptroller General
CNS	Conselho Nacional de Saúde - National Health Council
CIB	Comissão Intergestores Bipartite - Bipartite Intergovernmental Commission
CIT	Comissão Intergestores Tripartite - Tripartite Intergovernmental Commission
CONASEMS	Conselho Nacional de Secretários Municipais de Saúde - National Council of Municipal Health Secretaries
CONASS	Conselho Nacional de Secretários Estaduais de Saúde - National Council of State Health Secretaries
COSEMS	Conselho de Secretarios Municipais de Saude – Council of Municipal Health Secretaries
DENASUS	Departamento Nacional de Auditorias do SUS – National Department of Audits of SUS
FIOCRUZ	Fundação Oswaldo Cruz – Oswaldo Cruz Foundation
FPB	Farmácia Popular do Brasil - Brazilian Popular Pharmacy Programme
FURP	Fundação para o Remédio Popular – Foundation for the Popular Medicines
HIV/AIDS	Human Immunodeficiency Virus

HIPERDIA	Programa Hipertensão e Diabetes - Hypertension and Diabetes Programme
IAFB	Incentivo à Assistência Farmacêutica Básica – Basic Pharmaceutical Assistance Incentive
IBGE	Instituto Brasileiro de Geografia e Estatística – Brazilian Institute of Geography and Statistics
INAMPS	Instituto Nacional de Assistência e Previdência Social - National Institute of Medical Assistance and Social Care
IPEA	Instituto de Pesquisa Econômica Aplicada - Institute of Applied Economic Research
NMP	National Medicines Policy
NOB	Normas Operacionais Básicas - Basic Operating Standards
NPPA	National Policy on Pharmaceutical Assistance – Política Nacional de Assistência Farmacêutica
OSS	Organizações Sociais de Saúde - Social Organization of Health
PAB	Piso da Atenção Básica -.Primary Care Quota
PACS	Programa de Agentes Comunitários de Saúde - Community Health Agents Programme
PFB	Programa Farmácia Básica - Basic Pharmacy Program
PNAD	Pesquisa Nacional por Amostra de Domicílio - National Household Survey
POF	Pesquisa de Orçamento Familiar - Brazilian Household Budget Survey
PSF	Programa Saúde da Família - Family Health Programme
RENAME	Relação Nacional de Medicamentos Essenciais - National Essential Medicines List
REMUME	Relação Municipal de Medicamentos Essenciais -Municipal List of Essential Medicines

SESAB	Secretaria de Saúde do Estado da Bahia – Bahia Health State Secretary
SUS	Sistema Único de Saúde - Unified Health System
TCU	Tribunal de Contas da Uniao – Court of Accounts of the Union
UBS	Unidade Básica de Saúde – Basic Health Unit
UNICEF	United Nations Children’s Fund
WHO	World Health Organization