

Federalism, the Economic-Industrial Health Care Complex and High-Cost Pharmaceutical Assistance in Brazil

Elize Massard da Fonseca ¹
Nilson do Rosario Costa ²

Abstract *Brazil has a relevant, although relatively unknown, special medicines programme that distributes high-cost products, such as drugs needed for cancer treatments. In 2009, the purchase of these medicines became the responsibility of the Brazilian Federal Government. Until then, there were no clear norms regarding the responsibilities, in terms of the management/financing of these medicines, of the Brazilian Federal Government and of the states themselves. This qualitative study analyses the policy process needed to transfer this programme to the central government. The study examines the reports of the Tripartite Commission between 2000 and 2012, and in-depth interviews with eleven key informants were conducted. The study demonstrates that throughout the last decade, institutional changes have been made in regard to the federal management of these programmes (such as recentralisation of the purchasing of medicines). It concludes that these changes can be explained because of the efficiency of the coordinating mechanisms of the Federal Government. These findings reinforce the idea that the Ministry of Health is the main driver of public health policies, and it has opted for the recentralisation of activities as a result of the development project implicit in the agenda of the Industrial and Economic Heal*

Key words *Decentralisation, High cost medicines, Special medicines, Development industrial and economic health complex*

¹ Escola de Administração de Empresas de São Paulo, Fundação Getúlio Vargas. Edifício Fundação Getúlio Vargas, Bela Vista. 01313-902 São Paulo SP Brasil. emassard@gmail.com

² Escola Nacional de Saúde Pública, Fiocruz.

Introduction

Brazil has a notable and recognised specialised medicines programme (previously known as exceptional or high-cost products) in Brazil's National Health Service. These are pharmaceutical products used in the treatment of rare diseases, generally having a high unit cost and/or technological density (protected by patents) and mainly produced by multi-national pharmaceutical industries. The distribution of these medicines currently deals with 23 illnesses. For example, they are used in the treatment of cancer, hepatitis C and minimise the risk of rejection of transplanted organs in patients with chronic renal failure. In 2009, this programme went through a phase of important reorganisation with the centralisation of the purchase of 43 high-value medicines grouped together by the Ministry of Health (MoH)¹ which, up until that point, was the responsibility of the individual states.

This article analyses the paradoxical process of recentralisation of the specialised medicines programme in Brazil. This recentralisation shows an unexpected shift in federal policy until that time dominant within Brazil's National Health Service [*Sistema Único de Saúde* or SUS]. The MoH opted for the verticalisation of the specialised medicines programme in the National Health Service in spite of the apparent impact on the decision-making autonomy of the regional governments and the weakening of organised regional interests.

According to institutional change literature, it is to be hoped that the change in federal ownership of a programme would take place in the event of the diagnosis of a crisis or loss of credibility, which was not the case here, as we have demonstrated. Moreover, as Arretche² suggests, the regional governments could have fostered coalitions of interest with the pharmaceutical industry on assuming the provision of services within the National Health Service. The existence of this regional interest would produce a veto point as regards any change made to the existing decentralised arrangement. In this sense, it is necessary to understand that the multinational pharmaceutical industry is one of the most important interest groups in the world, making large donations to political campaigns and which acts in a highly-politicised environment³ (Pharmaceutical Assistance policies and regulations affect this sector more than any other public policy, such as labour policy). Therefore, it is reasonable that the states had their own interest in main-

taining the purchase of these products regionally. Moreover, this is an important health issue and one which could reap political returns as suggested by classic literature on Federalism, in which competing federal states stimulate inter-governmental negotiations in electoral competitions⁴.

It is surprising, as this article demonstrates, that the decision to recentralise the purchase of specialised medicines by the Ministry of Health in 2009 did not face strong regional rejection. What changes in the political agenda made it possible for the Ministry of Health to take this important decision within the Brazilian National Health Service? Why did the Ministry of Health take on the onus of the financial responsibility of a programme with such a large impact on its expenditure? Why did the regional governments not veto the recentralisation of the purchase of medicines?

Table 1 shows the paramount representation of the specialised medicine component in the total expenses dedicated to pharmaceutical assistance: approximately 40% in the last few years. There has been a significant growth in expenditure on these medicines throughout the years in Brazil. While in 2003, the Ministry of Health spent approximately R\$ 500 million on specialised component products, in 2008 this figure jumped to R\$ 2.3 billion (representing 38% of the pharmaceutical assistance costs). As it was a

Table 1. Evolution of the allocation of resources (R\$ Billions) with the specialised medicine programme on the total of pharmaceutical assistance, Brazil 2003-2012.

Year	Specialised Medicine	Total Pharma Assistance	Special. Med/ Total PA (%)
2003	0,51	1,95	26%
2004	0,80	3,07	26%
2005	1,13	3,37	33%
2006	1,33	4,41	30%
2007	1,92	5,25	37%
2008	2,27	5,90	38%
2009	2,60	6,32	41%
2010	3,22	6,98	46%
2011	3,46	8,35	41%
2012	4,01	9,67	42%

Source: Data provided by the Minister of Health, Department of Pharmaceutical Assistance in October 2013, through the Citizen Assistance System. Obs. Previous to 2003 there was not specific plan, the allocation of resources for this component was within the Cap of Medium and High Complexity activities.

shared finance programme up to 2008, the states contributed 9% of the costs (202 million R\$)⁵.

Even though part of the financing was the responsibility of the Ministry of Health, throughout the years the competence of acquiring the medicines and managing the programme remained with the State Health Secretariats. Up until 2009, there were no clear norms as regards the responsibilities of the two separate levels of government in the management and financing of this programme. What is relevant to this analysis is that, from 2009, the Ministry recentralised the purchase of certain medicines considered strategic (components having high financial impact) and included the municipalities in the acquisition of certain medicines of lesser associated value and generally for initial use in the treatment of illnesses¹. The federal states remained responsible for 88 medicines used in the treatment phase following outpatient treatment of the disease and the municipalities responsible for 82 medicines (forming part of the National List of Essential Medicines and which make up the first line of care in the treatment of illnesses covered by this programme). The new regulations quashed the intergovernmental co-financing scheme. As shown in Chart 1, Group 1 medicines became entirely financed by the Ministry of Health, Group 2 came under the exclusive responsibility of the federal states and Group 3 under tripartite management.

Studies on the specialised medicines programme in Brazil mainly discuss its technical aspects^{5,6} as well as the institutional changes and changes in norms and the evolution of the public costs or even the growing legal claims for these medicines⁷⁻⁹. Little is known on the political process which brought about these decisions

or effects, particularly as regards the division of competences between the Brazilian Federal Government and the federal states in the provision of these products. This article aims to understand the negotiation process between the Union and the states in the provision of specialised medicines in Brazil.

Methodology

This study has to be both retrospective and in depth in its approach given that this is an object of study which has been little explored in publications. Approaching the study from this angle also affects the manner in which the analysis is constructed. A qualitative methodology is the most adequate in this case as it will allow us to understand the viewpoint of the different players in relation to the specialised medicines programme; the facilitating factors and institutional limits to its development, amongst other things.

The first part of this study is comprised of document-based research. All the minutes of the Tripartite Inter-managerial Commission (TIC) between 2000 and 2012 (approximately 120 minutes), of which 24 constitute records of deliberations on the specialised medicines programme. It was also possible to find out the preferences of the managers at each of the three levels of government throughout the years. The TIC is the official arena of deliberation on policies which involve shared management, its minutes are public and are made available on line. Moreover, the position adopted by the representative of the Federal States Health Secretariats (CONASS in its Brazilian initials) and Municipal Health Secretariats (CONASEMS) in these meetings rep-

Chart 1. Responsibilities of levels of government over the Specialised Medicine Programme divided by group of medicine.

Group	Planning	Acquisition	Storage	Distribution
1A	SHS	MoH	MoS- SHS	MoH- SHS
1B	SHS	SHS	SHS	SHS
2	SHS	SHS	SHS	SHS
3	MHS	MOH-MHS	MoH/SES/MHS	MoH/ SHS/MHS

MoH = Ministry of Health, SHS = State Health Secretariat, MHS = Municipal Health Secretariat.
Source: Minister of Health³.

resent the associated preferences of these agents. Data relevant to the demands of CONASS and CONASEMS was collected as regards the specialised medicines programmes, what problems were registered and the deliberations of the TIC as regards this programme.

In addition, a review of newspaper articles published between 1990 and 2020 was carried out on the subject (specifically of the newspapers *Valor Econômico* [Economic Value] and *Estado de São Paulo* [State of Sao Paulo]). Data was collected on the lack of specialised medicines, demands made by civil society and by businessmen and government decisions. Ministerial Directives and publications of the Ministry of Health were also consulted on this subject. The document-based research identified which players were engaged in the formulation and implementation of specialised medicines policies and their preferences and it also served as guidance on a baseline of interviewees to be contacted for this study.

In the second stage we carried out eleven semi-structured interviews, between March and November 2011, with leadership informants representing the pharmaceutical industry, the government and specialists in the decentralisation of health care. The interviewees were selected via an earlier stage based on references made by other informants and those of the websites of the State Health Secretariats and the Ministry of Health, according to the following criteria: having some participation in policymaking in specialised pharmaceutical assistance, some experience in pharmaceutical assistance and having the competence to pass comment on the questions being investigating (e.g. personal involvement in a particular event). This phase was important to better understand the pharmaceutical negotiation process and clarify the management process of this programme, identified during the document-based research. Moreover, we asked the Ministry of Health for information on the Pharmaceutical Assistance budget (deflated by the Amplified Consumer Price Index) which served to demonstrate the evolution of the federal budget for this programme.

The analysis of data was carried out in conjunction with the collection of information^{10,11}. Each interview was transcribed in full, after the conversation took place, which allowed for the immediate reflection on the information provided and the identification of the issues raised. Moreover, it was important to refine the interview script as the new data was collected. This was the first stage of the systemisation of data,

organised into categories (according to the aforementioned theoretical parameters). Different sources of information and the comparison of data were used as tools to increase the validation of the analysis.

This research was conducted according to the requirements of the Ethical Review Board of the executing institution and the sponsor agency. The names of the interviewees were excluded from this analysis to ensure confidentiality. By adopting these procedures, we guarantee a high level of ethical cautions and confidentiality

Results

The results are organised into two sections, first the period of formation and development of the specialised component of the Pharmaceutical Assistance are discussed, with emphasis on responsibilities held at each government level. The second section discusses the process of the centralisation of the purchase of specialised medicines and the interests involved in this process. The historical narrative allows us to observe the changes, both operational and legislative, and the demands at play.

The evolution of regional management in high-cost Pharmaceutical Assistance

The exceptional medicines programme was created in early 1980s and the acquisition of these products was the responsibility of the federal government through the regional superintendencies of the National Institute of Social Medical Assistance [INAMPS]¹², linked to the Ministry of Social Welfare. Such medicines were classified as any drug which was not included in the National List of Essential Medicines. The decision to provide these products was based, in the main, on a demand from patients with chronic renal failure whose needs were not covered by way of the list of medicines¹³.

After the 1988 Constitution, the federal states took on the responsibility of dispensation of these medicines (initially, the federal government's responsibility to reimburse their acquisition was not stipulated). The Ministry of Health had already taken on responsibility for health policy, formerly the responsibility of the Ministry of Social Welfare). This decision led to a shortage of supply, mainly due to the high cost and necessity to import these products⁶. This event motivated the Ministry of Health, through the Minis-

terial Directive of 1993, to centralise the purchase of two medicines for use in chronic renal failure and renal transplant patients (cyclosporine and human recombinant erythropoietin) and more than 15 drugs and 31 presentations. From there, a list of exceptional medicines was established.

The first patient associations were also organised in this period. As for chronic renal failure groups, these were already mobilised around the cause, groups such as carriers of Gaucher's disease organised themselves into associations to demand government-provided treatment¹³.

At the end of the 1990s, adjustments were made to the programme to improve its financial management and control. The High-Complexity Procedures Authorisation System (known as Apac)¹⁴ was established and, subsequently, an annual physical and financial programme was requested from the federal states as regards exceptional medicines, which remained under federal financing although the acquisition of the same was a decentralised process. There were also no protocols established for the use of these medicines, the states themselves being responsible for the drawing up of norms. This scenario generated significant differences between the amounts provided by the federal government and the amounts spent in the federal states, in terms of the care of these patients^{5,13}.

Another important change took place in 2002, in terms of the programme costing, with the introduction of co-financing between the Brazilian Federal Government and the federal states. Ministerial Directive GM/MS No. 1318/2002¹⁵ defined a set of medicines in terms of procedures, substantially increasing the number of medicines offered. However, no clear rules were established on the proportion of financing by the Brazilian Federal Government and that of the federal states and neither were criteria established to measure the participation of the federal bodies⁵. An analysis of the TIC minutes suggested that this ministerial directive was not agreed upon by the managing bodies. In contrary, in the minutes of the August 2001 meeting, CONASS's preoccupation was with the growing number of legal actions for the provision of specialised medicines, which were burdening the State Health Secretariats' budget. For the first time it was suggested that the Ministry of Health should assume responsibility for the purchase of these products¹⁶.

In 2003, due to the growing legal claims within the federal states and the difficulties for the managing bodies to meet the provision of these products, the possibility of centralised purchase

of two medicines: Imiglucerase (for Gaucher's disease) and Pegylated Interferon (for hepatitis) was discussed in the TIC, as well as the demand from CONASS that the criteria for clinical inclusion of patients be revised as well as for the revision of the amounts provided by the Ministry of Health. In the October meeting, it was established that the Ministry of Health would assume responsibility for Imiglucerase, allowing a saving of 15 million R\$ to the states.

In 2004, a report from the Brazilian Federal Government Court of Auditors pointed out significant differences in purchase prices of four specialised medicines across thirteen State Secretariats, as in the case of Cyclosporine, the difference between the highest and lowest unit price was of 252.24%, while the federal states counterparts varied from -20% (Minas Gerais state) to 182% (Amapá state) in relation to the reference price¹⁷. This may be indicative of the reduced bargaining power with suppliers in some states purchasing on a smaller scale, the distance from the distribution centre, access difficulty or even negligence or corruption in public agencies. Moreover, severe deficiencies were observed in the management and control systems of this programme within the states, which were, in the main, not computerised. Some State Health Secretariats developed their own computerised systems but these were not interlinked between states. In the same way, the dispensation units carried out manual controls, to the detriment of important decision-making information. For example, the lack of information as regards the number of patients cared for, the medicines dispensed and resource allocated, which had a detrimental effect on the acquisition programme, and which was, in turn, reflected in the quality of the Pharmaceutical Assistance programme.

The Brazilian Federal Government Court of Auditors study also pointed to insufficient resources in order to guarantee state-to-state equivalence. At that time, the federal government was in the process of laying down a table of fixed prices payable per dispensed medicine, independent of state acquisition (normally lower than acquisition price), which was defined as based on the quantity of medication invoiced and the prices established by ministerial directives (e.g. GM/MS no. 1318/2002¹⁵ and SAS/MS No. 921/2002¹⁸). In other words, the distortions in the acquisition process, linked to the amounts provided by the Ministry of Health were punishing those federal units purchasing medicines on a smaller scale (with less negotiating power with

the supplier). It is important to point out that no agreements were identified in the TIC minutes as to state-by-state percentages.

In 2003, the media announced, on several occasions, a shortage of medicines for hepatitis¹⁹. Moreover, an analysis of the invoicing for Levodopa (for the treatment of Parkinson's disease) for that year, based on Apac's data in the Outpatients' Data System showed that in the states of Amazonas, Ceará, Goiás, Mato Grosso do Sul, Minas Gerais and Santa Catarina presented no invoices in the period for these illnesses (the state of Ceará reported no patients attended)¹⁷.

These inequalities in the purchase and provision of specialised medicines were pointed out by the CONASS as being the result of the difficulty in agreeing a policy on specialised medicines and the resources for the same, particularly as regards the increase in the list of products provided²⁰. At that time, proposals were suggested such as a national price bank, a revision of the table based on 100% of the lowest acquisition price in government procurement and a wider agreement of the Pharmaceutical Assistance policy. However, no proposal contemplated the centralisation of the purchase of these medicines.

Finally, several studies on the specialised medicines programme point to the lack of transparency and a lack of criteria for the inclusion of these products in the National Health Service list throughout this period^{5,13,17}. Only in 2002 were a Clinical Protocol and Drug Guidelines drawn up, an essential process for the establishment of criteria for the inclusion of patients onto the programme and the coordination of their entry in an equal manner in all states. The flawed incorporation of new medicines and the lack of drug protocols sometimes caused regional inequalities in the provision of these services.

The Director of the Pharmaceutical Assistance Department recognised that many of the problems faced in the management of the specialised medicines programme were as a result of its precarious management throughout the years, both by the federal states as by the Ministry of Health²¹. As presented in this section, the existing proposals to ameliorate the programme were directed towards maintaining ownership by the states of the acquisition and provision of these medicines. Legal actions which were placing a burden on the states were the motivation behind a discussion in the TIC on the possibility of the centralisation of the purchase of two medicines.

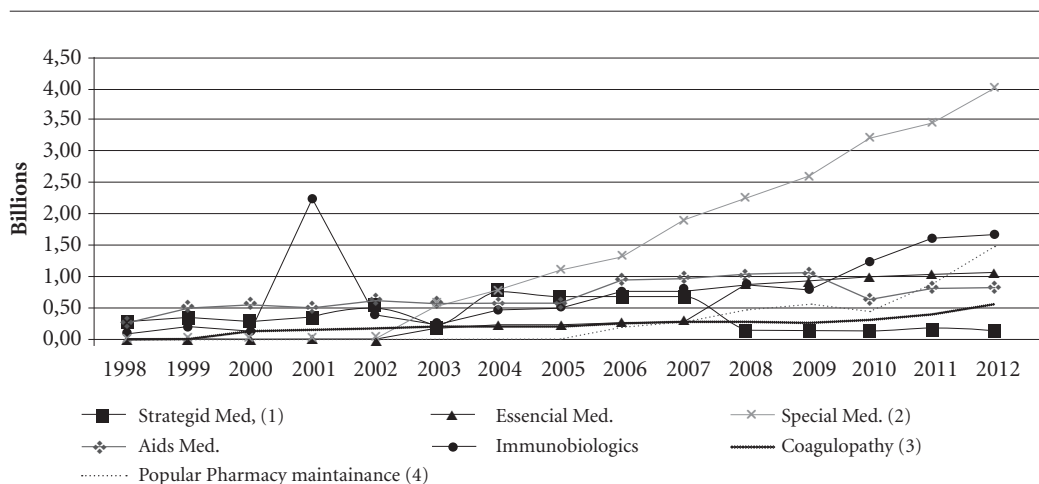
Nevertheless, the arguments of the CONASS suggested that this was less a question of imput-

ing the political costs of the programme (negative image resulting from uncountable legal claims) than a public management problem. There was incapacity in the states to provide these products due to their financial cost and limited bargaining power with the pharmaceutical industries. In other words, there was huge inequality in the provision of these medicines within the Brazilian states. Moreover, CONASS has never demanded the complete recentralisation of the purchase of these medicines, but it did demand changes to the co-financing model, for example, the increase of the Ministry of Health's participation in the financing of the programme.

Finally, the data in Graphs 1 and 2 demonstrates the evolution of the budget allocated for the Pharmaceutical Assistance programmes between 1998 and 2012. It is possible to observe that there was a significant increase in the budget for specialised medicines throughout the years as well as the proportion of the amounts allocated for this component out of the total amount of the Pharmaceutical Assistance. Given that we had no access to numbers on the volume of patients covered by this programme, it is difficult to conclude whether there was an increase in the demand for specialised medicines or if these amounts refer to the increase in the price of the medicines. Moreover, until 2009 this data reflected solely on the allocation of the Ministry of health as regards these medicines, and excluded the participation of the states. It is also important to bear in mind that the Ministry of Health increased the list of medicines offered throughout this period. Nevertheless, the data demonstrates that the specialised medicine component represents the main investment in medicines of the Ministry of Health.

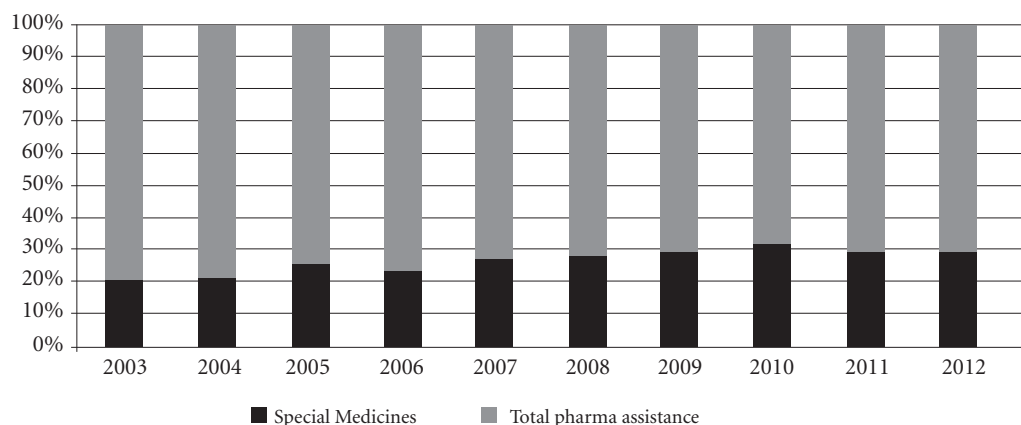
Reformulation of the Specialised Medicines Programmes and the Economic-Industrial Health Care Complex

It was only in 2006, when the Ministry of Health began the process of constructing a Technology Management Policy^{22,23} and the creation of a Commission for the Incorporation of Technology into Healthcare²⁴, that the management of the specialised medicines component gained visibility. These decisions were taken as part of a broader agenda on the Economic-Industrial Health Care Complex. This issue raised in the agenda of the MoH in 2003 during the 2nd National Conference on Science and Technology and Health^{25,26}. Commitments with health poli-



Graph 1. Evolution of allocated resources (R\$ Billions) on Pharmaceutical Assistance Programmes, Brazil, 1998-2012.

Source: Data provided by the Minister of Health, Department of Pharmaceutical Assistance in October 2013, through the Citizen Assistance System. ⁽¹⁾ There is no disaggregated data on the strategic and basic component for the period from 1998 to 2002. ⁽²⁾ Regarding the special medicine component, previous to 2003 there was not specific plan, the allocation of resources for this component was within the Cap of Medium and High Complexity activities. ⁽³⁾ There is no data available before 2000 for coagulopathies medicines. ⁽⁴⁾ The values for Popular Pharmacy Programme were adjusted as to include the allocation of the National Health Fund (FNS) and Fiocruz. The numbers informed by the Science, Technology and Strategic Supplies Secretariat included only the FNS.



Graph 2. Proportion of allocation of resources with specialised medicines on the total of pharmaceutical assistance, Brazil, 2003-2012.

Obs. Previous to 2003 there was not specific plan, the allocation of resources for this component was within the Cap of Medium and High Complexity activities. Source: Data provided by the Minister of Health, Department of Pharmaceutical Assistance in October 2013, through the Citizen Assistance System.

cies (such as the supply of medicines to pharmaceutical assistance programs) triggered initiatives to promote the industrial development of the pharmaceutical sector²⁷. As these authors suggest, the launch of *Mais Saúde* in 2007 boosted

this agenda through an inter-sector program to develop the local production of medicines and medical devices.

According to the minutes of the TIC, discussions about the Economic-Industrial Health Care

Complex predated the decision to reformulate the specialised medicines component or rather, a change in the agenda of the Ministry of Health served as a stimulus for the re-evaluation of the role of the federal states and of the Brazilian Federal Government in the acquisition of these products. This sequence of events is important as it demonstrates that despite the deficiencies presented in the previous section, at no point did the Ministry of Health demonstrate its interest in centralising the purchase of these medicines.

The first step to reforming the specialised medicines component took place in 2006 following a study by the Ministry based on values provided by the federal states, which aimed to link these values with the diseases covered. It was not possible to have access to this study; however, the data was presented in the TIC meeting of August 2006. It is clear that no criteria existed defining the programme and that there were 105 medicines (in 230 presentations) were provided though the Apac²⁸. Amongst the 230 presentations, 41 products represented 81% of the expenditure, and 24 of these were registered on the Ministry's table at a price lower than that of the lowest purchase price provided by the states. On the other hand, 14% represented a price on the table which was higher than the lowest price. It was also observed that several states bought medicines at prices higher than the factory price, with a variation of 180% in prices among states for the same product.

In the same meeting, it was discussed the shared responsibility of the Brazilian Federal Government and the federal states for the specialised medicines programme. Once again, the purchase of Pegylated Interferon (for the treatment of hepatitis) was found in the minutes, with the federal states expressing difficulty in buying this product and an increased pressure from civil society demanding the scale up in its provision and its dispensing criteria. CONASS argued that there was a difficulty in buying this product within the states due to the different price for each federal unit and refuted criticism from the industry that there were delays in payments of tenders from within the states. This information was corroborated by interviews with representatives of the pharmaceutical industry who suggested that states like Rio de Janeiro delayed by nearly two years their payment of a tender, whereas Santa Catarina was the most reliable in this sense (personal communication). In response to this questioning by CONASS, the Ministry of Health forwarded the issue to the Technical Chamber of

the TIC to formulate a proposal, reminding them that "the underpinning principle to guide them should be the partnership between the Ministry of Health and the federal states, which means assuming both the burden and the rewards in the negotiation of responsibilities"²⁴.

In the context of the drawing up of the technology management plan and the discussions of the TIC, the Ministerial Directive no. 2577/2006²⁹ was issued in October 2006 and, for the first time, rules for the execution of the programme were defined. There was an effort to determine the Federal Government's responsibilities in relation to requests, authorisation, provision and execution. Even so, the models for each stage were not clearly established. For example, the Clinical Protocol and Drug Guidelines remained obligatory for the dispensation of medicine; however, it wasn't clear how the state should carry out the technical assessment of these requests⁵.

What this Ministerial Directive suggests is that the Ministry of Health, at that time, opted to maintain the co-financing model with the federal states. However, it recognised the urgent necessity to improve the organisation of the normative and operational rules of the programme. In the subsequent years, the Ministry of Health reorganised the specialised medicine component by way of "care guidelines" and the Clinical Protocol and Drug Guidelines were the key instrument in this classification. This process took place in conjunction with the revision of the basic component of the Pharmaceutical Assistance, concluding that 17 specialised medicines should be provided at local level. This decision generated discussion in the TIC given that the CONASEMS pointed out its concern regarding the capacity of municipalities of assuming this responsibility²⁸.

It was only in 2009 that the Programme went through large-scale reorganisation with the centralisation of 43 medicines of high unit price¹. The question is: why centralise the purchase of these medicines which were clearly going to increase Federal Government expenditure, without there being a demand for the same by the states? The motivation basically came from the drawing up of policies for the Economic-Industrial Health Care Complex, wherein the centralisation of the purchase of these medicines was a key instrument to the viability of projects such as the public-private partnerships in the production of strategic and specialised medicines. The Economic-Industrial Health Care Complex proposed 40 partnerships for the development of the pharmaceutical production sector (Pharma-

ceutical Development Programme), stimulated by the Ministry of Health, via its purchase power, to develop strategic drugs and medicines³⁰. For this to take place, it was necessary to guarantee the producers (partnerships between public and private laboratories) the purchase of medicines manufactured in the Pharmaceutical Development Programme.

The decision to centralise was one of the priority issues of the TIC in 2009³¹. It can be observed in the contents of the minutes of the meeting that the Department of Pharmaceutical Assistance of the Ministry of Health was the main articulator of this discussion; even CONASS and CONASEMS highlighted its importance in the pushing through of this decision³².

Sao Paulo State Health Secretariat managers and technicians suggested that the Ministry of Health was, in fact, the main articulator of the proposal to centralise the purchase of specialised medicines, and it did not meet with any large regional opposition. When asked whether there had been any difference of opinion as regards this decision, an interviewee suggested that there were no salient queries posed by the states. At that time, Luiz Barradas, the manager of São Paulo, had doubts on the working of this institutional rearrangement, given that the state had an organised process of programming and purchase as well as already holding a significant purchase power, therefore one which was more representative. Thus, the reports suggest that there was less of a political worry than an administrative one in the state of São Paulo. They also observed that although there is a quantitative gain which comes with centralised purchase, on the other hand, the states remain with the burden of distribution and logistics. In the past, the pharmaceutical industries carried out the distribution to the health units designated by State Health Secretariat which, under the new arrangement, is now responsible for the stocking and distribution of the medicines, generating a cost which the federal states did not bear before. One interviewee weighed up that the centralisation may have helped patients in states in which the Pharmaceutical Assistance programme was less organised.

In short, there was a reorientation of the role of the public laboratories³³ which ceased to solely produce essential medicines, to instead produce medicines of higher added value by way of partnerships with private companies offering technology transfer, with a guarantee of purchase of their product by the federal government. By 2013, 88 Pharmaceutical Development Programmes

were signed for the manufacture of medicines, 24 of which were for biological products. If, on the one hand, the states lost decision-making power in the specialised medicines programme, on the other they received incentives to improve technological development in their regions.

Discussion

The aim of this article was to understand the negotiation process between the states and the Brazilian Federal Government in the provision of specialised medicines in Brazil. Little is known on this political process which involved the various players. This paper has begun with the premise that interests on how the responsibilities for this programme are distributed would hold the status quo despite the interests of the federal government.

Qualitative evidence collected suggested that this belief cannot be sustained. The findings of this study are aligned with recent studies on federalism in Brazil where a distinction between the responsibility for public policy (the right to act) and the authority to take decisions (the right to decide) demonstrate that regional governments are highly constrained by central government decisions³⁴.

Data collected via documents and interviews suggests that between 1993 and 2009, all the discussions held on the specialised medicines programme were centred on improving the role of the federal states in their provision. The process of negotiation was incipient, similar to that observed in other debates³⁵ or they proposed solutions which would maintain the co-financing system.

The evidence suggests that it was only with the impulse of the agenda of Brazil's Worker's Party [Partido dos Trabalhadores] of bringing together the industrial policy and the of science and technology policy for health sector, that the Ministry of Health changed its preference as regards the federal states and opted to centralise these medicines. Among the various institutional changes necessary for to put this agenda into practice, the centralisation of the purchase of specialised medicines was at the centre of the debate. Therefore, there are strong indications that the predominance of the federal executive in the formulation of health policy was the most important explanatory element in the understanding of why the states let the ownership of a large part of this programme fall from their grasp.

Therefore, this study concludes that the health policy is not as decentralised as was supposed in all healthcare activities. Or, to put it another way, although the states and municipalities have it at their discretion whether or not to adhere to the policies of the Ministry of Health, the instruments of formulation and implementation of policies remain vertically centralised. This study demonstrates that regulation of the specialised medicines programme, throughout the years, was decided via Ministerial Directive. There were reports on the inefficiency of state management and alternatives on how to solve the problem, which were kept to adjustments made along the same trajectory (or rather maintaining the ownership of the programme in the hands of state managers). The decision to centralise it was not accidental, and neither did it have anything to do with efficiency, institutional crisis or exterior pressures, but rather the response to an agenda considered to be strategic by the Ministry of Health: the creation of policies for the Economic-Industrial Health Care Complex. In other words, if it were not for the new developmentalist agenda of the Ministry of Health, it is unlikely that the centralisation of the purchase of these medicines would have taken place.

Another finding of this study was linked to the growing legal actions for the provision of specialised medicines, although this was not the main objective of analysis of this article. Some studies on the subject refer to the lack of knowledge of the judges as to the organisation of the Pharmaceutical Assistance programme and the pressure of patient groups and industry groups which would lead to legal actions^{9,36,37}. Nevertheless, nothing has been discussed on the unequal provision of medicines in the states and the inefficiency in the implementation of the specialised medicines programme throughout the years³⁸ which left a gap through which these products were acquired via the justice system. If there had been clear criteria to define the programme beneficiaries, rules on the incorporation of new technologies and a clear definition of intergovernmental functions would the preferences of the industries and patients have found shelter under the justice system? This study suggests that the inertia of the Ministry of Health in relation to this programme created fertile ground for the increase in legal claims.

Conclusion

The analysis of the negotiation process of the specialised medicines component of the Pharmaceutical Assistance programme suggests that the decision to centralise it only took place due to a reorientation of the agenda of the Ministry of Health, with focus on the productive development of the pharmaceutical sector. In other words, it was not due to a rupture in the health system or from pressure from the states (or interest groups) but given the institutional mechanisms of federal coordination.

This article enriches studies on Federalism which suggest that the Brazilian Federal Government has maintained great authority over the direction of Brazilian health policy³⁹. Both studies on the Pharmaceutical Assistance programme and those on the decentralisation of health remain largely normative. It is vital that the understanding of the demands and choices of the agents involved in the formation of policy as regards the pharmaceutical sector are included in analytical models in order to shape sustainable interventions in the years to come.

As this was an analysis of national policy, it was not possible to look at the dilemmas of re-centralisation of the specialised medicines programme state by state. This can be investigated through future regional comparative studies. Also, it still remains to be seen what the distributed effects of this centralisation will be, which could be explained in future by the analysis of historical series' of expenditure by state, federal government and the volume of patients cared for under this programme. The constant updating of the list of medicines offered by the National Health Service, the publication of the criteria for patient inclusion in the programme and the monitoring of the costs and expenditure are important governance practices for the legitimisation of the developmentalist agenda in the democratic context. Moreover, clear guidelines as to the competences of the regional governments as regards this programme are equally crucial to guarantee access to the medicines.

Collaborations

EM Fonseca worked in the research design, data collection and analysis and preparing this manuscript. NR Costa worked in the research design, analysis and preparing the manuscript.

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