

National Medicines Policy in retrospective: a review of (almost) 20 years of implementation

Daniela Moulin Maciel de Vasconcelos ¹
Gabriela Costa Chaves ¹
Thiago Botelho Azeredo ²
Rondineli Mendes da Silva ¹

Abstract *Pharmaceutical services and the formulation of a medicines policy are SUS areas ensured by the organic health care law 8,080/90. Thus, after a widely participative process, involving stakeholders, the National Medicines Policy (NMP) was approved in 1998 by Ordinance 3,916. The NMP presents directives and priorities, aligned with organic health care law, which should guide the federal, states and municipalities actions to achieve the policy goals. Considering almost 20 years of the NMP, this paper took stock discussed some of the directives in light of the SUS principles. It was not the objective to provide an exhaustive review of all the activities performed during this period. The authors tried to get close to those that have brought advances and dilemmas, with potential risk of regression. Efforts to implement an ambitious agenda applied to pharmaceutical services were identified. This agenda tried to deal with different challenges like the dynamics of the pharmaceutical market and the operation of pharmaceutical services to guarantee the supply of medicines aligned with principles and directives of SUS.*

Key words *Pharmaceutical services, National drug policy, Health policy, Unified Health System*

¹ Departamento de Política de Medicamentos e Assistência Farmacêutica, Escola Nacional de Saúde Pública, Fiocruz. R. Leopoldo Bulhões 1480, Manguinhos. 21041-210 Rio de Janeiro RJ Brasil. daniela.vasconcelos@ensp.fiocruz.br

² Observatório de Vigilância e Uso de Medicamentos, Faculdade de Farmácia, Universidade Federal do Rio de Janeiro. Rio de Janeiro RJ Brasil.

In the early 1990s, policies were set in motion to implement the Unified Health System (SUS), guided by the principles of the 1988 Brazilian constitution. Medicines and other health technologies were, and still are, at the core of the healthcare system, contributing to disease prevention and care.

The organic healthcare law 8,080/90 ensured comprehensive healthcare within the various SUS areas, including pharmaceutical services and the formulation of a medicines policy. According to recent regulations, assuring universal, equal and comprehensive access to pharmaceutical services (PS) within SUS requires seeking healthcare in public facilities, prescriptions in compliance with the National Medicines List and the therapeutic guidelines, and dispensing in facilities appointed by the SUS management.

Given the dismantling of the Medicines Center (*Central de Medicamentos* – CEME) in 1997, the Ministry of Health (MoH) formulated, in a widely participative way, the National Medicines Policy (NMP), approved in 1998 by Ordinance 3,916. The goal of the NMP is to ensure the safety, efficacy and quality of medicines, promote their rational use and access by the population to those medicines considered essential. Even though we consider the directives and priorities of this policy to be adequate, as with any other government policy, there are challenges and weaknesses in its implementation. We highlight particularly the under-funding that, since the advent of SUS, has been a constant in public healthcare services and measures, and the imbalance in the spending on medicines in the private and public systems.

Furthermore, healthcare is technology-intensive, and Brazil is known to be dependent on imported technologies, against the background of the simultaneous existence of new and old diseases, from the infectious to the chronic-degenerative. This demonstrates the complexity of building and implementing a social agenda applied to pharmaceutical services.

The authors believe that, in a thematic edition on medicines, it makes sense to take stock of the almost 20 years of the NMP. In an opinion article about a policy of this magnitude, there is the risk of placing more value on the scope of implementation than on the depth. For this reason, we chose to discuss some of the specific directives in light of the SUS principles. It is not our intention to provide an exhaustive review of all the activities performed during this period, but rather to highlight a few that have made significant progress or pose specific dilemmas and the potential risk of regression.

The first issue is related to ‘Rename’, the National List of Essential Medicines, which in 1999 was subject to review, after almost two decades. Comare, a Technical and Multidisciplinary Committee to Update Rename, was also established. Proposals to include or exclude medicines were submitted to public consultations based on essentiality of medicine to address the population’s main healthcare needs, and the adoption of evidence-based medicine.

Rename has been published since 2000, and updated in 2002, 2006, 2008 and 2010¹. It was used as a guideline by sub-national entities when formulating their own lists, and contributing to the selection of medicines. The list covered from primary care through secondary and tertiary care. In 2010, it included some 593 items, including products for oncology and ophthalmology.

Having defined comprehensive pharmaceutical services within SUS, with a direct impact on its activities, Law 12,401 and Decree 7,508 both signed in 2011, led to the absorption of the Comare functions by Conitec (the National Committee of Technology Incorporation), and Rename became a positive list of financed medicines rather than a guiding list for clinical and management practices.

In 2012, Rename expanded to include products funded through the Components of Pharmaceutical Services (Basic, Strategic and Specialized), the national List of Health Products and the National List of Medicines for Hospital Use, totaling 809 items. Nevertheless, this increase does not mean that the list suitably addresses all the population’s healthcare needs. The “new Rename” as a funding list, is susceptible to pressure for the incorporation of new technologies instead of a focus on needs based on priorities¹.

We argue that more than a simple development of criteria and procedures for selecting medicines for SUS, between 1998 and 2012 there was a shift in policy from the concept of ‘essential medicines’ as the organizing criterion of pharmaceutical services, which favored universal care, towards incorporating technologies, betting on innovation as an enabler of comprehensive pharmaceutical care².

This movement is partly the result of intense judicialization of pharmaceutical services within SUS². Although using the court to pressure for availability is an alternative for access to medicines, it may favor the non-rational use of medicines and increase costs, consumes the majority of the PS funds in a number of cities, and impacts the organization of medicines management. This

in turn requires creating administrative sections dedicated to compliance with the demands issued by the courts.

A NMP directive for refocusing pharmaceutical services put in motion measures to promote access to medicines by expanding availability within the SUS network. This change in focus meant extending the principle of decentralization to medicines management, which in turn required assigning responsibility for funding, procurement and distribution².

As a result, mechanisms to fund SUS, and especially pharmaceutical services, have been slowly reorganized with a direct impact on pharmaceutical services activities and management. Since 2006, funding has been split into three components: Basic, Specialized and Strategic.

Basic pharmaceutical services focused on supplying the primary healthcare facilities considering the coverage expansion of activities with tripartite funding (federal, state, municipal) and implemented by the municipalities. The annual *per capita* amount increased 391%, from R\$ 2.00 in 1999 to the current R\$ 9.82.

The strategic component inherited and continued the centralized structure for planning public healthcare actions, meaning federal selection of medical products and their funding and procurement. The other two administrative levels (state and municipal) are responsible for bottom-up programming and for the actual dispensing².

The Specialized component (formerly high-cost or exceptional), was an initiative to ensure comprehensive care, and responded to pressure to add new, often high-cost technologies, by defining treatment guidelines that may or may not include the products demanded. However, the rationale for making decisions for Specialized components within CONITEC, became the standard for selecting and standardizing all SUS products, illustrating the already mentioned shift from the concept of essential to incorporation. This component is funded in part by the states, and their contribution has been the fastest growing over the years. In 2003 the MoH spent R\$ 500 million, and in 2015 R\$ 6 billion, an almost 1,200% growth³.

The Strategic and Specialized components include medicines that are under a monopoly (subject to patent protection), and are at high prices. This explains in part the greater weight of these components in public medicines spending. This is a challenge, and requires a price regulation agenda for these products that takes into consid-

eration the need to increase the government's bargaining power, which includes addressing the patent barriers and strategies for local production⁴. For example, in 2007, the government issued the first and only compulsory license for efavirenz, an anti-HIV medicine, resulting in savings for the MoH and an opportunity for local production.

The scope of PS measures shall not however be limited to procurement and distribution. Based on these arguments and as a result of the 1st National Conference on Medicines and Pharmaceutical Services, in 2004, the National Policy on Pharmaceutical Services (PNAF) was approved. A number of National Medicines Policy actions were grouped under the conceptual umbrella of pharmaceutical services. PNAF reinforced the legitimacy of the Executive to address other healthcare activities². In 2003, the Department of Pharmaceutical Services was created within the Department of Science, Technology and Strategic Products, focusing on the MoH programming and procurement, which previously had been fragmented across a number of programs.

In 2004, the so-called Popular Pharmacy Program (PFPB) was created, providing a new mechanism to fund (via co-payment) and organize (through partnerships with private pharmacies) pharmaceutical services. Due to their geographic scope, these partnerships were responsible for the growth and expansion of the PFPB. This growth was also a result of the decision in 2011 to wave co-payment for hypertension, diabetes and asthma medicines. The PFPB has raised a number of concerns related to the competition with public pharmacies facilities in SUS, its cost compared to government procurements, and the return of the MoH as the central entity in supplying medicines⁵.

All the aforementioned initiatives reflect an increase in medicines coverage for diseases that are widely prevalent in Brazil. For example, data from the National Survey on the Access, Use and Promotion of the Rational Use of Medicines (PNAUM) in Brazil shows full access to medicines for about 98% of people with high blood pressure⁶.

Despite this progress, most of the spending on medicines in Brazil comes from out-of-pocket household budgets. In 2007, household spending on medicines totaled around R\$ 45 billion, and in 2013 almost R\$ 80 billion. Government spending was far below this, close to R\$ 5 billion in 2007 and R\$ 9.5 billion in 2013. Household spending on medicines was equivalent to 1.6% of the GDP (Gross Domestic Product) in 2010, and 1.5% in

2013, while government spending was only 0.2% of the GDP in both 2010 and 2013⁷.

This approach to pharmaceutical services organization and funding shows some of the contradictions and conflicts in the policies designed to provide universal access to medicines. The imbalance between public and private spending could be seen as failure of the public policy to provide medicines coverage and protection to meet the population's health needs. However, there is little clarity regarding the patterns of use and rationality of private spending on medicines. These criteria limit the expansion of public spending on healthcare.

Two other NMP directives - sanitary medicine regulation and the safety, efficacy and quality of medicines provided the basis for the creation of the National Health Surveillance Agency (Anvisa) in 1999 through the enactment of Law 9,782, and incorporated the responsibilities and functions of the former National Health Surveillance Secretariat. The role of the agency as a market regulator expanded with its involvement in the secretarial function of the Pharmaceutical Market Regulation Chamber (CMED).

Numerous regulations have been issued on the requirements and procedures for medicines registration and renewal, in particular the introduction of generic medicines - criteria ensuring greater certainty regarding the safety and efficacy of the medicines available in Brazil, and to stimulate competition. However, the expectation that multisource brand-named (*similar*) medicines would withdraw from the market and be replaced by generics as a result of the generics strategy never materialized.

The requirement that generics be submitted to bioequivalence tests was viewed as an entry barrier and a possible risk of the reduction in number of suppliers⁸. The existence of *similar* medicines enabled offering products at lower prices over the years⁹. Since 2015, *similar* medicines have been required to pass bioequivalence and other tests, becoming in practical terms "branded generics".

Other mechanisms to make supply more flexible have been presented over time, possibly responding to pressure from the regulated industry. These included extending the period for renewal of registration from five to ten years, faster medicines registration, and shorter time to authorize clinical trials, etc.

Another directive is the promotion of rational use of medicines, which are a broad field of individual and articulated measures, within the

concept proposed in the NMP. This involves patients, healthcare professionals, managers, and health-related institutions and systems.

The first national course teaching the rational use of medicines (NAF/ENSP, ANVISA, WHO) was held in 2002. In 2007, the National Committee for the Rational Use of Medicines was created, leading to a wide array of materials for user education and training of healthcare professionals. Other initiatives include Congresses and the "Lenita Wannmacher" Award for the Rational Use of Medicines; and, in 2015, the Working Group for Pharmaceutical Services in Pediatrics, which was an effort to cover an important global gap in the rational use of medicines. Regulatory strategies were implemented for the prescribing and dispensing of medicines, gradually expanding the list of medicines subject to special control and monitored on a national basis through the National System to Manage Controlled Substances. There is now enhanced control of antimicrobial prescription and dispensing, with prescriptions retained by the pharmacy and recorded in a registry. This policy is in effect in both the public and private sectors.

The directive related to promoting medicines local production is recognized at different moments in these two decades. First, the approval of the Generics Law in 1999 incentivized the domestic private manufacturing sector, increasing the supply of generics and fostering competition. Second, in 2004, marked the start of a new cycle of industrial policy in Brazil, translated in the federal Industry, Technology and Foreign Trade Policy (PITCE), which considered the pharmaceutical industry to be strategic. Third, in 2008, the Healthcare Industrial Complex was included in the Ministry of Health program entitled *Plano MaisSaúde - Direito de Todos* (More Health - a Right of All).

The focus of stages in the production chain of pharmaceuticals has differed over the years. The generics policy focused on the private manufacturing industry, and did not prioritize the active pharmaceutical ingredient (API) industry, which actually retracted in the 1990s. The decentralization of pharmaceutical services for primary health care had a negative impact on public production of medicines⁴.

In 2009, Product Development Partnerships (PDP) were created with a focus on transferring technology to public manufacturers, including API industry as a target. Priority products for local production were those adopted by SUS because one of the incentives for technology trans-

fer was the exclusive access to the government market for medicines⁴.

From the point of view of social control, this PDP initiative was not very transparent along the various stages in the process - from listing the products and partners involved, through the actual contracts signed by the parties. There is also a mismatch in time between when strategic products for local production are defined (the list is reviewed annually), and when technology is transferred and absorbed by the public manufacturer. PDP agreements can take up to 10 years to bear fruit, which is particularly important given the speed at which the selected technologies are incorporated and then can become obsolescent.

The directive for scientific and technological development produced, in 2004, at the 2nd National Conference on Science, Technology and Innovation in Health, and provided the basis for formulating the National Policy for Science, Technology and Innovation in Health in 2008, and approval of the National Agenda of Priorities in Health Research (ANPPS).

The ANPPS illustrates how the principles of SUS guided the formulation process and enabled approving an agenda guided by healthcare needs, rather than a model of prioritization based on market potential. The 24 sub-agendas are not limited to the development of new technologies, and address several issues that are priority for public health. Between 2003 and 2005, 42.7% of the funds the MoH invested in this agenda went to 4 sub-agendas focused on medicines¹⁰.

The directive for the development and training of human resources is key to make the NMP operational. The MoH published calls for courses to train human resources in pharmaceutical services across the country. For example, the federal universities offered both face-to-face and distance courses on this topic. The cities and states are also promoting PS training. This theme gained relevance and in 2007 the National Board of Health Secretaries (Conass) published a book on pharmaceutical services, which was updated in 2011 and 2015.

To increase the incorporation of pharmaceutical services in healthcare networks, considering comprehensive care, the National Pharmaceu-

tical Services Qualification Program (Qualificar - SUS) was created in 2012. The program is based on the themes of structures, education, information and care. The courses offered by *ProjetoSentinela* (Sentinel Project, 2002) that focus on pharmaceutical services management, pharmacovigilance and the rational use of medicines have contributed to gathering data on the performance of medicines use outside of the controlled environment of clinical trials. The goal was to avoid the harmful effects of improper use.

In conclusion, the overview presented herein shows efforts to implement an ambitious agenda based on the National Medicines Policy, illustrating its importance as the guiding document across different governments. The directives and priorities of the NMP address a double challenge. On the one hand, dealing with the dynamics of the pharmaceutical market based on regulation, and on the other, ensuring the supply of medicines is aligned with the operations of the public healthcare system. Thus, the National Medicines Policy is a constant unfinished agenda.

Although the principles of the Unified Healthcare System (SUS) are recognized in the different initiatives listed, we also recognize that making a policy operational brings with it a number of contradictions and the risk that some of them may be compromised. Increased funding of the different components of pharmaceutical services, together with expanding formal guarantees of access to medicines reflect a greater commitment to universal and comprehensive care. On the other hand, stratifying funding by component and the uneven increase in spending across these components may threaten equity, as the proper use of the more expensive medicines requires access to specialized care and diagnostic supports that are not yet universal.

The progress made, happened in a context of an underfunded SUS, a situation that is likely to worsen following the approval of EC 95/2016, which froze the federal government's budget for primary expenses for 20 years. Funding is core for an effective healthcare policy, including pharmaceutical services. Therefore, there is a risk that the achievements to date may become nothing more than a fond memory.

Collaborations

DMM Vasconcelos, RM Silva, TB Azeredo and G Costa Chaves participated in all stages, including conception and designing, writing, editing and final review of the article.

References

1. Santos-Pinto CDB, Ventura M, Pepe VLE, Osorio-de-Castro CGS. Novos delineamentos da Assistência Farmacêutica frente à regulamentação da Lei Orgânica da Saúde. *Cad Saude Publica* 2013; 29(6):1056-1058.
2. Azeredo TB. *Política Nacional de Medicamentos no Brasil: da estrutura normativa à reflexão dos agentes sobre o processo de implementação* [tese]. Rio de Janeiro: Escola Nacional de Saúde Pública Sergio Arouca; 2012.
3. David G, Andreilino A, Beghin N. *Direito a Medicamentos. Avaliação das Despesas com Medicamentos no Ambiente Federal do Sistema Único de Saúde entre 2008 e 2015*. Brasília: Inesc; 2016.
4. Chaves GC. *Interfaces entre a produção local e o acesso a medicamentos no contexto do Acordo TRIPS da Organização Mundial do Comércio* [tese]. Rio de Janeiro: Escola Nacional de Saúde Pública Sergio Arouca; 2016.
5. Silva RM, Caetano R. Costs of Public Pharmaceutical Services in Rio de Janeiro Compared to Farmácia Popular Program. *Rev Saude Publica* 2016; 50:74.
6. Mengue SS, Bertoldi AD, Ramos LR, Farias MR, Oliveira MA, Tavares NUL, Arrais PS, Luiza VL, Pizzol TD. Access to and use of high blood pressure medications in Brazil. *Rev Saude Publica* 2016; 50(Supl. 2):8s.
7. Instituto Brasileiro de Geografia e Estatística (IBGE). *Conta-Satélite de Saúde Brasil*. Rio de Janeiro: IBGE; 2013.
8. Mendoza Ruiz A, Osório-de-Castro CGS. *Medicamentos: falando de qualidade*. Rio de Janeiro: ABIA; 2008.
9. Miranda ES, Pinto CDBS, Reis ALA, Emmerick ICM, Campos MR, Luiza VL, Osório-de-Castro CGS. Disponibilidade no setor público e preços no setor privado: um perfil de medicamentos genéricos em diferentes regiões do Brasil. *Cad Saude Publica* 2009; 25(10):2147-2158.
10. Silva RM, Caetano R. Um exame dos fluxos financeiros do Ministério da Saúde em pesquisa e desenvolvimento (2003-2005), segundo a Agenda Nacional de Prioridades de Pesquisa em Saúde. *Cad Saude Publica* 2011; 27(4):687-700.

Article submitted 26/10/2016

Approved 16/02/2017

Final version submitted 18/02/2017