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REFLECTIVE ANALYSIS ARTICLE

PUBLIC POLICIES OF MEDICATIONS IN THE UNIFIED HEALTH SYSTEM AND UNIVERSALITY OF RIGHTS

POLÍTICAS PÚBLICAS DE MEDICAMENTOS NO SISTEMA ÚNICO DE SAÚDE E A UNIVERSALIDADE DE DIREITOS

POLÍTICAS PÚBLICAS DE MEDICAMENTOS EN EL SISTEMA ÚNICO DE SALUD Y LA UNIVESALIDAD DE DERECHOS

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ABSTRACT

Objective: to provide reflections about the challenges and possibilities for expanding universal access to medications under the Unified Health System (SUS) through social policies and genuinely national health. ***Method***: study of theoretical and critical reflection, with prior literature review based on scientific studies, manuals of the Brazilian Ministry of Health and World Health Organization reports. ***Results***: the extensive study of possible thematic enable reflection on the limits of operational policies of medication in SUS and the universal right to health, and challenges to expanding access to medicines. ***Conclusion***: several factors demonstrate that the Brazilian government, although regulated the medication policy, are not still stimulated in the right way, limiting their full practicability. It is critical to innovative strategies are implemented to expand access to medication in the country in order to resolve differences in their access. ***Descriptors***: Public Health Policies; Medication Policy; Pharmaceutical Services; Right to Health.

RESUMO

Objetivo: proporcionar reflexões acerca dos desafios e possibilidades de ampliação do acesso universal a medicamentos no âmbito do Sistema Único de Saúde (SUS) por meio de políticas sociais e de saúde genuinamente nacionais. ***Método:*** estudo de reflexão teórico-crítico, com prévia revisão de literatura fundamentada em estudos científicos, manuais do Ministério da Saúde Brasileiro e Relatórios da Organização Mundial de Saúde. ***Resultados:*** o estudo extenso da temática possibilitou a reflexão sobre os limites da operacionalidade das políticas de medicamentos no SUS *e* o direito universal a saúde, e sobre os desafios para a ampliação do acesso universal aos medicamentos. ***Conclusão:*** vários fatores demonstram que o Estado brasileiro, embora tenha regulamentado as políticas de medicamentos, ainda não as estimula da forma devida, limitando sua exequibilidade plena. É fundamental que sejam implementadas estratégias inovadoras para ampliar o acesso aos fármacos no país, de forma a dirimir as disparidades no acesso a estes. ***Descritores:*** Políticas Públicas de Saúde; Política de Medicamentos; Assistência Farmacêutica; Direito à Saúde.

RESUMEN

Objetivo: proporcionar reflexiones acerca de los desafíos y posibilidades de ampliación del acceso universal a medicamentos en el ámbito del Sistema Único de Salud (SUS) por medio de políticas sociales y de salud genuinamente nacionales. ***Método:*** estudio de reflexión teórico-crítico, con previa revisión de literatura fundamentada en estudios científicos, manuales del Ministerio de Salud Brasileño e Informe de la Organización Mundial de Salud. ***Resultados:*** el estudio extenso de la temática posibilitó la reflexión sobre los límites de la operabilidad de las políticas de medicamentos en SUS y el derecho universal a la salud, y sobre los desafíos para la ampliación del acceso universal a los medicamentos. ***Conclusión:*** varios factores demuestran que el Estado brasileño, a pesar de haber reglamentado las políticas de medicamentos, todavía no las estimula de la forma debida, limitando su plena viabilidad. Es fundamental que sean implementadas estrategias innovadoras para ampliar el acceso a los fármacos en el país, de forma a dirimir las disparidades en el acceso a estos. ***Descriptores:*** Políticas Públicas de Salud; Política de Medicamentos; Asistencia Farmacéutica; Derecho a la Salud.

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INTRODUCTION

The Unified Health System (SUS) provides universal and equitable access to health actions and services.[1] In the same way, the universal and free access to essential medicines standardized by SUS is guaranteed by the Brazilian Constitution and Article 6 of Law 8080/90, which ensures integrated care, including pharmaceutical care.[2] Access to medicines has a complex area of public and private actors, which play different roles depending on the economic, political and social environment of the country.[2,3] In addition, access to medicines is given by their availability, its geographical acceptability and accessibility, as well as the purchasing power of people.[4]

Access to essential medicines is recognized by the United Nations as one of the five indicators related to progress in ensuring the right to health.[5] However, it is still considered critical the global situation of access to essential medicines. Although access to health care is a fundamental human right, including access to medicines, the World Health Organization (WHO) estimates that about two billion people are lack of regular access to these medicines.[6] In the XXI century, it is estimated that one in three people worldwide do not have access to such inputs, with the worst situation occurring in low and middle-income countries where this proportion can reach 50%.[4,6]

Epidemiological studies show that access to medicines is associated with female7, adulthood,[2,7] black or mulatto,[7,8] with chronic diseases[2,8] and number of medical consultations.[8] Also, socioeconomic status and underuse of medications are associated strongly and inversely with their access, which shows that a large portion of the population has SUS as the only alternative to make possible the necessary therapy.[9]

In Brazil, despite the implementation of public policies from the 1990s, such as the National Medicines Policy (PNM), the National Pharmaceutical Assistance Policy (PNAF), the Policy of Generic Medicines and the Popular Pharmacy Program, the available to continuously medications and the correct amount to the population´s needs is transposed as a challenge.[10] Furthermore, private spending on acquisition of medicines is significant in the country.[7]

A Brazilian study published in 2013 aimed to describe the prevalence and factors associated with medicine users access in SUS that were prescribed in the public system. In this study the researchers analyzed data from the National Survey by Household Sample held in 2008, in the country, whose sample consisted of individuals who had medicine prescription in SUS in the two weeks preceding the interview (n=19,427). The dependent variable of this study was access to all of medicine prescription in the system. They found that out of 19,427 individuals interviewed, 7,111 (35.9%) did not receive prescribed medications and the Northern Region was the one with the lowest rate of access (37.2%), while 3,615 (18.7%) had access to only some of the medicines they needed. Among the 10,726 individuals who did not have full access to medicine prescriptions, 78.1% had resorted to the private sector, while 8.8% were without medication because they have not money to buy them. However, almost half of respondents (45.3%) received the medicine free in public area, with a higher prevalence of access among residents in the South (56%), black skin color (20%), low income (59%) and less educated (65%) than those with registered home in the Family Health Strategy (24%).[3]

Insufficient access to medicine is directly associated with worsening of health status, greater use of additional therapies, increase in the number of returns to health services and additional spending on treatments.[7,8] It should be noted that most of the epidemiological studies on medicines are restricted to study the prevalence of use without assessing how indeed is the access to medicines. The big challenge in this area is to determine the difficulties of access also for those who did not use medicines, that is also assessing the prevalence of medication that the individual needs to use, but failed to use due to lack of access.[2]

OBJECTIVE

- To provide reflections about the challenges and possibilities for expanding universal access to medicines in SUS through social policy, health policy and genuinely national developers.

METHOD

Study of theoretical and critical reflection about the challenges for universal access to medicines in SUS. Previously, a comprehensive review of the literature based on scientific studies, books, manuals Ministry of Health (MOH) and WHO reports was conducted. The extensive and exhaustive study of the subject enabled to emerge two areas for reflection: a) the universality of the right to health and limits of the operation of public policies on medicines in SUS; b) Challenges and

opportunities for the expansion of universal access to medicines in SUS.

RESULT AND DISCUSSION

● The universality of the right to health and the limits of operation of public policies of medicines in SUS.

The Federal Constitution of 1988 represents a historical reference in terms of recognition of social rights in Brazil. After almost 30 years since its enactment, it is undeniable expanding access to these rights.[11] However, the universal right to health is well established from the point of view of Brazilian legislation, but between statements of purpose and reality, there are still gaps almost insurmountable.[12]

Law 8080 (1990) and its changes by Law 12,041 (2011) and 10,424 (2002) is about the universality of this system as the right of the population to different forms of access or restoration of their health, such as the availability of health professionals, equipment and inputs for health, including medicines.[11] After almost three decades of SUS institutionalization, there is a movement of great social and constitutional achievement with respect to public participation in health care, since the participatory nature of managing this system was a process built on decades of fights in a permanent building movement.[12] Thus, intense social participation was SUS master key from its origin, with articulation of social movements in the 1970s and 1980s, culminating in the reform of the health sector.[1,13]

Health emerged as a citizen issue from SUS, and political participation as a condition of its exercise. In addition, participating in the decision-making process and exercise control on the implementation of public policies are fundamental practices to enlarge the possibility to gain new social rights, and to rely on these achievements also minimize inequalities and inequities still rooted in Brazilian society.[14] Thus, public policies are essential to be effective and build the SUS.[12]

At the present juncture, Brazil approaches the Social Welfare model also called Welfare States or Keynesian State which was characterized by trying to reconcile democracy and capitalism, where the state acted as a protective agent and intervening in all areas of society. Thus, by referring to the proposal of that model, collective is highlighted, since policies developed in response to the process of modernization of Western societies and consisted of political interventions in the economy and social distribution aimed at promoting security and equality among citizens held by distributive policies.[15] In that context, the National Medication Policy (PNM) is a government attempt to act in this way, promoting access to essential medicines equitably, essential fact for comprehensive care.[16]

For over 40 years, Brazil seeks to apply a medication policy that, despite the market predominantly oligopolistic and dominated by multinational pharmaceutical companies, guaranteeing the population access to essential medicines.[10] However, there is still the dominance of large multinational companies that dominate the market national in different segments and therapeutic classes.[17] The Big Pharma´s, big pharmaceutical conglomerates, divide among themselves a billionaire market and act primarily by the search for greater profitability, investment power and market penetration.[18] It is an urgent need for a state interventionist philosophy more effective and resolute in this unequal situation between the domestic versus international production of medicines.

The Brazilian pharmaceutical industry has undergone important changes, especially in recent decades, such as the approval of PNM[16], the enactment of the Generics Law, the approval of the National Policy of Pharmaceutical Assistance (PNAF) and later the National Herbal Medication Policy.[19] Another important guideline implemented with the publication of PNM was the reorientation of Pharmaceutical Care and its suitability for decentralized model of health management, currently in effect in Brazil. This policy established in addition to the basic guidelines, priorities and responsibilities of the Pharmaceutical Assistance for federal, state and municipal SUS managers.[10] The reorientation of Pharmaceutical Care, based in the care of local needs and priorities, aimed at developing activities related to promoting people´s access to essential medicines and should not be restricted to the acquisition and distribution of medicines.[10]

Another attempt in order to strengthen access to medicines and stimulating the growth of national industry was the origin of the Generic Medicine Policy. This policy was implemented in Brazil in 1999 with the aim of encouraging commercial competitiveness, improve the quality of medicines and facilitate people´s access to medication treatment.[20] Although it is right, such a policy should also move towards overcoming the two key gaps in the health industrial complex, that is, the local business base of innovation and

commitment to the health conditions of the population.[21]

There is no denying the contribution of generic medicine policy and strengthening the pharmaceutical state to expand access to medicines and strengthening of the national medicine policy, however, access to medicines in the country within the SUS is still insufficient.[3]

● Challenges and possibilities for expansion of universal access to medicines in SUS

An attempt to increase the population´s access to medicines is the largest stimulus and the performance of state medicine industries, besides reducing the need to import medicines with consequent reduction of value and therefore greater access. The production of medications by the public can contribute to resolving the problems in the supply of certain medications, such as neglected diseases, typical of developing countries.[22]

Another interesting and promising strategy that can be viewed is the investment in inputs and genuinely national medicines in the medication area. Brazil has the greatest plant genetic diversity of the world, a mega biodiversity.[23] It is precisely in this context that the National Herbal Medicine Policy[19] comes as a complementary practice with scientific support and whose use has spread exponentially throughout the world, especially in developing countries.[24] Moreover, this growth denotes paradigm shifts towards holistic, as these practices contribute to the integral health care. It is estimated that more than half the world´s population have ever used some form of complementary practice.[24]

In Brazil, with the need to integrate Western medicine to complementary health practices, as well as to ensure completeness in health care, the Ministry of Health created the National Policy on Integrative and Complementary Practices (PNPIC-SUS)25, approved in 2006 aimed to implement the safe use of these practices and create opportunities to use natural methods in primary health care, which can provide a holistic and humanized care, with emphasis on the therapeutic relationship, the integration of the human being with the environment and in the overall promotion of self-care.[19,25] The herbal medicine is one of the members of the complementary practices in PNPIC-SUS.

Herbal medicines represent the most efficient form of distribution and access in herbal medicine. In Brazil, to an herbal be marketed, it must be registered in the National Health Surveillance Agency (ANVISA), responsible for quality, safety and efficacy of the product, similar to those of other medications. Here, it is important to note the odd regulation regarding the registration of these types of medication in the country. In addition to the random clinical tests, Brazil offers a legal and innovative opportunity of using ethno-pharmacological information and even techno-scientific documentation to prove the efficacy and safety of these medicine.[26]

The current public policy in Brazil recommends promoting the popularization of the use of medicinal plants and herbal medicine in primary care, however, with efficacy, safety and conservation practices of medicinal biodiversity.[27] Furthermore, consideration of popular knowledge is an important paradigm breakdown, because while it is rescued a type of knowledge that has been built gradually over centuries through the use of medicinal plants, is also popular participation in SUS strengthened since the population is very receptive to engaging in activities relating to medicinal plants.[27]

Brazil has geographical, climatic, cultural, technological and scientific potential which is a paradox dependence on pharmaceutical ingredients or medicines for the largest medicine access of the population. It is corroborated by the fact that the cost of herbal medicines be lower than the medicines and the possibility of adding financial returns to traditional populations, such as indigenous and maroon, since their knowledge can be used in the construction of the medicine.[28]

It is emphasized the opportunity for innovation to public and national private sectors. There are many medicinal plant species in use by the Brazilian population for decades or even centuries and still do not have official records in the country and there are plants with pharmacological potential even been discovered. Added to this, the use of purchasing power of the state and improving the regulatory framework with a view to supporting innovation and the establishment of new financing instruments to the productive sector are among the new guidelines that put health as a strategic space policy.[28]

In Brazil, the regulatory and developmental strategies were implemented by the conservative elite, facilitated by a bureaucratic-corporatist network control classes and social protection. Thus, to date, there are not full or satisfactory universalization of social rights and citizenship. Major challenges continue to put

a new Brazilian Health Reform and SUS consolidation as public, universal, equal, full and quality health.[29] In the medium and long term it should have the opportunity in the gradual change in this scenario if there is a State strong and democratic for the establishment of a new social contract.[1,29]

It should be noted the favorable position of the Brazilian State in the following aspects: a) the country has mega-diversity vegetal genetics and cultural diversity of ethnic groups and secular knowledge in the use of medicinal plants; b) it has technology park, infrastructure, human resources in science and technology sufficient for research and production of new medicines on a large scale and diversification; c) it has innovative legislation for the registration of herbal medicines. These three notes allow a future optimistic scenario for the population´s access to medicines at low cost by the state, since it is effectively grounded by participation and popular composition.

It is seen that the community participation is broader than the formal spaces of social control, in order to expand alliances with popular movements, with NGOs, with the various departments and public agencies control. Therefore, there is a pressing need to propose strategies aimed at the empowerment and liberation of all social actors intertwined in SUS construction and consolidation.[12]

Indeed, the adoption of a medicine policy in the country requires as main base the free, universal and equal access to medicines for the entire population, with an emphasis on citizenship and social justice. This access should be guided by the real needs of the population served by the public health service. However, the daily practice of public health services also reveals how much it is difficult to ensure access to medicines constitutionally guaranteed to users of SUS, pointing to the gap between legal and real SUS.[15]

After 27 years of the enactment of SUS and more than a decade of creation of National Medicine Policy, it is clear that the Brazilian State still needs to surmount problems mainly arising from economic policy, which has put limits on the feasibility of medicine policy and social security, lying far to offer responses to the social issue regarding the inequality, especially the deprival of rights. These elements directly compromise the universal and equitable access to medicines and the materialization of the medicine policy.[15]

CONCLUSION

There is still much to do for the Brazilian health system becoming universal. However, SUS is a health system in development that continues to fight to ensure universal and equitable coverage. As the private sector participation in the market increases the interactions between the public and private sector, they create contradictions and unfair competition, leading to ideologies and opposing goals (universal access versus market segmentation), which generate negative equity in access to health and health conditions services.

For the Brazilian health system overcoming the challenges, it is essential a greater political mobilization to restructure the financing and redefine the roles of the public and private sectors. In other words, it urges a new financial structure and a thorough review of public-private relationships, so the greatest challenge facing the SUS is political. Issues such as financing, public-private joint and persistent inequalities cannot be resolved only in the technical sphere. The legal and normative bases have already been established and has already acquired enough operational experience. Now we need to ensure to SUS, their political, economic, scientific and technological sustainability.

Besides the financial issue and among the various challenges of the SUS today, this article sought to address the population´s access to medicines because it marked the national potential in this area. However, besides not achieving universal access to medicine treatment, it still needs huge sums for the import of pharmaceutical ingredients as well as the expensive medicine purchases of the State of large national companies. Several factors were listed, showing that the state, although regulated public medicine policies, it have not yet stimulate the due form, limiting their full feasibility. It is essential to be implemented innovative strategies to increase access to medicines in the country in order to resolve disparities in their access.

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