

## NATIONAL DRUG POLICY (PNM) UNDER THE VIEW OF HUMAN RIGHTS

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### ABSTRACT

The aim of this study was to identify if there is symmetry between the actions of the National Medicines Policy and the Human Rights guidelines. We used the cross-sectional study, with data collection from 2008 to 2017, which considered the demographic, social, economic variables, drug dispensing, and which had as sources the National Policy of Medicines, the National Policy of Pharmaceutical Assistance, the 2008 National Household Sample Survey of the Brazilian Institute of Geography and Statistics; and the National Survey on Access, Use and Promotion of Rational Use of Medicines. Regarding the results, we highlight the Popular Pharmacy Program of Brazil created in 2004 that served about 47,416,735 users by the end of 2017, ie approximately 23% of the Brazilian population had access to the medicines they needed as a result of the implementation. of this program. Thus, it was concluded that the National Medicines Policy has been improving access to medicines over the years, as the National List of Essential Medicines (RENAME) is updated every two years, in line with the World Organization guidelines. of health.

**Keywords:** Access to Medications. Pharmaceutical care. Rational Use of Medications. Essential Medicines. Human rights.

### INTRODUCTION

Attention to public policies aimed at medicines in Brazil came through Law 8.080 of 1990 that created the Unified Health System (SUS), with the purpose of

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guaranteeing full, universal, equal and free access to health services, and brought the formulation of drug policy as one of its objectives (BERTOLDI et al., 2016, p. 2).

Continuing, in the year 1993 was published Decree No. 793 by the Presidency of the Republic, seeking to favor the reduction of drug prices and highlighted the generic name. This Decree was repealed in 1999 through Decree No. 3181 which ratified drug policies by establishing and disposing of generic drugs (BRASIL, 1999).

In addition, the National Medicines Policy (PNM) instituted by Ordinance No. 3.916 of 1998, of the Ministry of Health, is a milestone for the implementation of actions capable of improving the health care of the population, as it aims “to guarantee safety, efficacy and quality of medicines, the promotion of rational use and the population's access to those considered essential ”(VASCONCELOS et al., 2017, p. 2610).

The name generic medicine is defined by Law No. 9,787 of 1999 (which amended Law 6,360 of 1976 dealing with the name of drugs) as a similar or innovative product developed when the patent protection was removed, either by expiration of the term. term or waiver of the patent owner to develop the drug (BRASIL, 1999).

That said, it is important to mention the data from the National Health Survey (PNS) 2013, where 41.5% of the Brazilian urban and rural population aged 18 years or older was diagnosed with hypertension, 11.1% with diabetes, 7.4% with some heart disease, 13.6% with depression and so on. This information is validated when analyzed from the perspective of the list of medicines available through the action “here is a popular pharmacy”, where medicines are sold to consumers at different prices.

The National Medicines Policy (PNM) has over the years, through the National List of Essential Medicines (Renama) improving access to medicines, since every two years, this relationship is updated, aligning with the guidelines. World Health Organization (WHO).

Rename 2018 contains 878 drugs, 11 of which have been included as new options for treating different diseases, including mucopolysaccharidosis type I, mucopolysaccharidosis type II, familial amyloidotic polyneuropathy related to transthyretin protein, and Wilson's disease. In addition, two drugs: adalimumab and everolimus were expanded in use. Already the artemeter (80 mg / mL, solution for injection) (CONITEC, 2018).

## **METHODS**

In order to reach the objective of identifying if there is symmetry between the actions of the National Medicines Policy (PNM) and the Human Rights guidelines, a cross-sectional study with a qualitative and quantitative approach was used. The study surveyed data from 2008 to 2017, and considered demographic, social, economic, drug dispensing, and private sector pricing. It was sourced from the National Medicines Policy (PNM), the National Pharmaceutical Assistance Policy (PNAF), the 2008 National Household Sample Survey (PNAD) from the Brazilian Institute of Geography and Statistics (IBGE) and the National Survey. Access, Use and Promotion of Rational Use of Medicines (PNAUM).

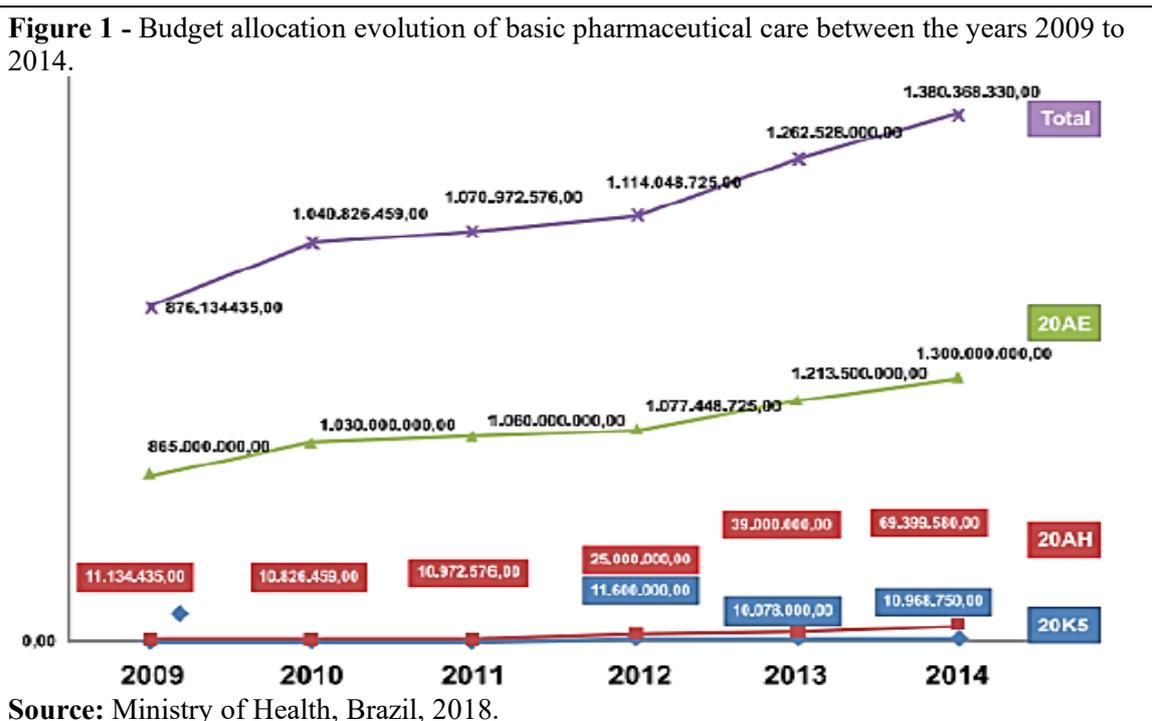
## **RESULTS**

The National Medicines Policy (PNM), whose purpose is “to ensure people's access to safe, effective and quality medicines at the lowest possible price” (PNM, BRAZIL, 2013), stands out as an important mechanism to minimize health problems. of the Brazilian population.

In this sense, the directive of the PNM (List of Essential Medicines - Rename) reached a level of visibility, since Decree No. 7.508 / 201 came to regulate Law No. 8.080 / 1990, stating that “Rename comprises the selection and standardization of medicines indicated to treat diseases or diseases within the SUS ”(BRASIL, 2011).

In addition, it is worth highlighting the guideline of the Pharmaceutical Care Reorientation, which comprises the universalization of access to medicines in the SUS through the decentralization of the drug dispensing process.

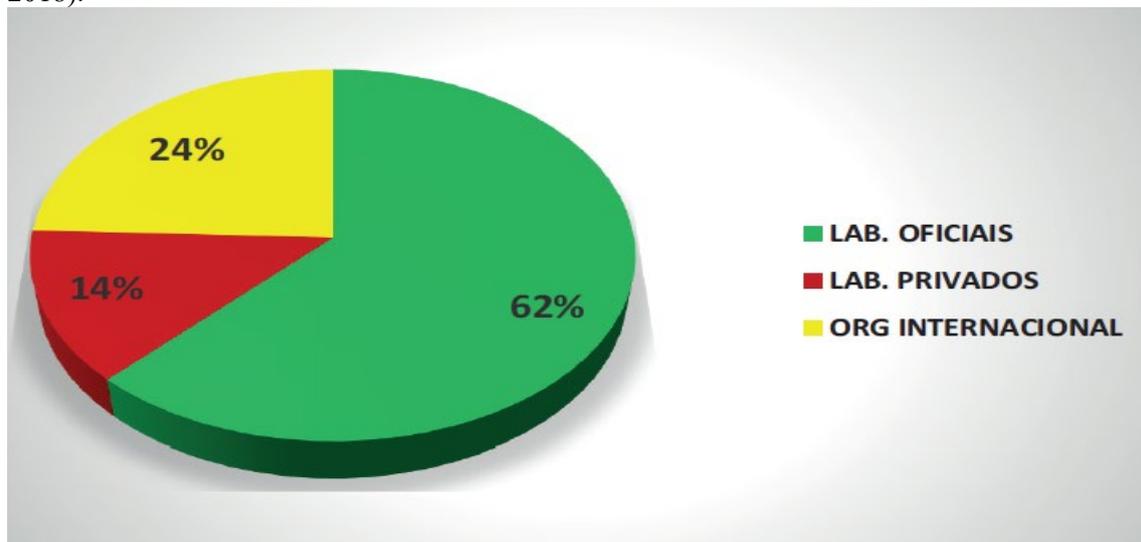
Thus, there was a budget increase of the Basic Component of Pharmaceutical Assistance (Cbaf), represented in the access to medicines of Primary Care (Action 20AE), qualification of Pharmaceutical Assistance (Action 20AH) and support to herbal medicines in the Single Health System (20K5) ( MINISTRY OF HEALTH, BRAZIL, 2018). This increase is observed in the figure below (BRAZIL, 2018):



Moreover, the Strategic Component of Pharmaceutical Assistance (Cesaf) plays an essential role in the implementation of the National Pharmaceutical Assistance Policy, since its purpose is to guarantee equal access to medicines and medical supplies (BRASIL, 2018).

In this sense, the strategies used by Cesaf for the implementation of pharmaceutical assistance are: I) monitoring access to medicines for neglected diseases or with little commercial interest; II) the centralization of the acquisition; III) production by official public laboratories and; IV) international acquisitions. The figure below shows the application of these strategies to promote access to medicines.

**Figure 2** - Routes of drug supply for neglected and poverty-related diseases, from 2005 to 2014 (Idem, 2018).



Source: Ministry of Health, Brazil, 2018.

In addition, another highlight in the Promotion of Rational Use of Medicines, consisting especially of the use of measures such as Educational Campaigns, Registration and Use of Generic Medicines, National Therapeutic Form, Pharmacoepidemiology and Pharmacovigilance and Human Resources. The table below shows the demographic characteristics of generic drug use (PNAUM, 2014).

**Table 1** - Prevalence of use of at least one generic drug according to demographic and socioeconomic characteristics.

| Variável                             | Prevalência de uso de genéricos <sup>a</sup> |           |         |
|--------------------------------------|--|-----------|---------|
|                                      | % <sup>b</sup>                               | IC95%     | p       |
| Sexo                                 |  |           | 0,013   |
| Masculino                            | 43,1   | 40,5–45,8 |         |
| Feminino                             | 47,0   | 44,9–49,0 |         |
| Idade (anos)                         |  |           | < 0,001 |
| 0-9                                  | 33,5   | 29,1–37,8 |         |
| 10-19                                | 33,0   | 26,8–39,2 |         |
| 20-59                                | 43,6   | 41,5–45,7 |         |
| ≥ 60                                 | 56,2   | 54,1–58,3 |         |
| Escolaridade <sup>c</sup>            |  |           | 0,819   |
| 0-8 anos                             | 45,5   | 43,4–47,6 |         |
| 9-11 anos                            | 44,4   | 40,4–48,3 |         |
| ≥ 12 anos                            | 45,9   | 43,1–48,6 |         |
| Classificação econômica <sup>d</sup> |  |           | 0,040   |
| A/B                                  | 42,6   | 39,5–45,7 |         |
| C                                    | 47,0   | 44,9–49,1 |         |
| D/E                                  | 44,6   | 41,3–48,0 |         |
| Região                               |  |           | < 0,001 |
| Norte                                | 32,7   | 28,5–37,0 |         |
| Nordeste                             | 37,9   | 35,8–40,0 |         |
| Sudeste                              | 49,9   | 46,8–53,0 |         |
| Sul                                  | 50,6   | 46,6–54,6 |         |
| Centro-Oeste                         | 45,1   | 41,9–48,4 |         |
| Total                                | 45,5   | 43,7–47,3 | -       |

Source: Pnaum, Brazil, 2014.

Thus, according to the National Survey on Access, Use and Promotion of Rational Use of Medicines (PNAUM), in the case of chronic diseases, such as hypertension, young adults, 20-39 years of age, appear to be younger. medical indication when it comes to drug therapy. This is what can be seen in the following table.

**Table 2** - Self-reported prevalence of hypertension, medical indication of drug treatment and use of hypertension drugs in the population aged 20 years or older in Brazil, according to sociodemographic characteristics.

|                         |                 | Prevalência de hipertensão arterial |             |        | Pessoas hipertensas com indicação médica de terapia medicamentosa |              |        | Pessoas hipertensas com indicação médica de terapia medicamentosa em uso de medicamentos |             |        |
|-------------------------|-----------------|-------------------------------------|-------------|--------|---|--------------|--------|--|-------------|--------|
|                         |                 | %                                   | IC95%       | p      | %   | IC95%        | p      | %  | IC95%       | p      |
| <b>Sexo</b>             | Masculino       | 18,5                                | [17,4-19,8] | <0,001 | 93,3  | [91,4-94,8]  | 0,349  | 93,4   | [91,5-94,9] | 0,024  |
|                         | Feminino        | 28,1                                | [27,0-29,1] |        | 94,2  | [92,9-95,2]  |        | 95,3   | [94,2-96,2] |        |
| <b>Faixa etária</b>     | 20 a 39 anos    | 5,97                                | [5,2-6,9]   | <0,001 | 78,0  | [71,1-83,6]  | <0,001 | 78,4   | [70,8-84,5] | <0,001 |
|                         | 40 a 59 anos    | 27,5                                | [26,3-28,8] |        | 93,4  | [91,9-94,7]  |        | 94,7   | [93,4-95,8] |        |
|                         | Mais de 60 anos | 59,0                                | [57,4-60,5] |        | 98,1  | [97,6-98,5]  |        | 97,6   | [97,0-98,1] |        |
| <b>Região do Brasil</b> | Norte           | 16,3                                | [14,6-18,1] | <0,001 | 92,1  | [89,36-94,1] | 0,086  | 91,38  | [88,1-93,8] | <0,001 |
|                         | Nordeste        | 21,7                                | [20,3-23,1] |        | 92,2  | [90,0-93,9]  |        | 91,13  | [87,6-93,7] |        |
|                         | Sudeste         | 26,0                                | [24,3-27,7] |        | 94,9  | [93,0-96,2]  |        | 95,59  | [94,2-96,7] |        |
|                         | Sul             | 22,4                                | [20,8-24,0] |        | 93,7  | [91,0-95,6]  |        | 97,37  | [96,1-98,2] |        |
|                         | Centro-Oeste    | 24,1                                | [22,0-26,3] |        | 92,9  | [90,4-94,8]  |        | 94,03  | [92,2-95,5] |        |
| <b>CCEB*</b>            | A/B             | 22,3                                | [20,4-24,3] | 0,126  | 95,1  | [93,0-96,6]  | 0,302  | 96,26  | [94,3-97,6] | 0,017  |
|                         | C               | 23,9                                | [22,8-25,0] |        | 93,4  | [91,9-94,7]  |        | 94,78  | [93,6-95,8] |        |
|                         | D/E             | 24,7                                | [23,1-26,3] |        | 93,6  | [91,5-95,2]  |        | 92,31  | [89,2-94,6] |        |
| <b>Total</b>            |                 | 23,7                                | [22,8-24,6] |        | 93,8  | [92,8-94,8]  |        | 94,6   | [93,5-95,5] |        |

Source: Pnaum, Brazil, 2014.

The Popular Pharmacy Program of Brazil (PFPB) created in 2004 by Decree No. 5,090, which regulated Law 10,858 of 2004, came to strengthen the National Pharmaceutical Assistance Policy (PNAF), because in 2006 after the publication of Ordinance No. 491, which authorized the federal government to form partnerships with the private pharmaceutical sector, instituted the action “here there is a popular pharmacy”.

Thus, the PFPB has already served about 47,416,735 users by the end of 2017, representing approximately 23% of the Brazilian population that had access to medicines as a result of the implementation of this program. In financial terms, the costs to the Ministry of Health with the PFPB in 2006 amounted to R \$ 34,723,571, rising to R \$ 2,815,000,000.00 in 2017.

## DISCUSSION

The realization of the right to health, including medicines, must be supported by an efficient health system, as a mechanism for the realization of fundamental rights and guarantees, such as the dignity of the human person. In this regard, Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR), where “the States Parties to the present Covenant recognize the right of every person to enjoy the highest possible level of physical and mental health” (BRAZIL, 1992).

The fundamental right to health is enshrined in Article 6 of the 1988 Federal Constitution as a social right. Health in a broad sense can be conceptualized as a state of functional harmony between a person's physical and psychic. The right to health is viewed under two panoramas: an objective that protects the holder against the arbitrariness of the state and individuals; and another installment that effects access to health (BATISTA et al., 2015).

O direito à saúde pode ser efetivado mediante políticas públicas<sup>2</sup> sociais e econômicas. Por este motivo, o direito à saúde, especificamente aos medicamentos, pode e deve ser garantido por meio de políticas públicas de assistência farmacêutica, que tratam da “proteção e recuperação da saúde individual e coletiva, tendo os medicamentos como insumos essenciais e visando à viabilização do acesso aos mesmos” (XAVIER et al, 2017).

Apesar do advento da Lei nº 8.080/1990 dando origem ao SUS, em clara convergência com a Constituição Federal de 1988, a Política Nacional de Medicamentos ainda não alcançou sua plenitude, pois:

Although the guidelines and priorities of this policy are considered appropriate, there are challenges and weaknesses in the implementation of any public policy. We highlight the underfunding trajectory with which public health actions and services have historically coexisted since the advent of the SUS and the imbalance between public and private spending on medicines (Ibid., 2017, p. 2609).

Thus, the national literature teaches that drugs are inputs that play a fundamental role in the health system, contributing to improve the quality of life of populations. Thus, regarding the generic drug, it can be said that it has translated into a government agenda for the promotion of access to essential medicines (MIRANDA et. Al., 2009, p. 2147-48).

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<sup>2</sup> Políticas públicas também abarcam uma série de questões setoriais que são entrelaçadas, assíncronas e espacialmente sobrepostas (FURTADO et al., 2015).

Therefore, the National Medicines Policy (PNM) is an important component of the National Health Policy (PNS), and aims to promote improvements in health care actions. To evaluate this policy it was necessary to include studies that analyze the efficiency and scope of promoting access to medicines and costs to the government. In this study, the subject consisted of demonstrating the convergence of the National Medicines Policy with the Human Rights guidelines.

## **CONCLUSION**

The study of the National Medicines Policy (PNM) allowed to evaluate the conformity between its actions and the Human Rights. With this, the results obtained, as well as the discussion pointed to the existence of symmetry between the PNM and the health-related human rights guidelines, promoting access to medicines.

PNM has implemented a basic pharmaceutical care model, and as stated in previous topics, decentralization of pharmaceutical care actions has gained prominence, not only for meeting local needs, but for encouraging states and municipalities to meet pre-established goals.

It is concluded, therefore, that the National Medicines Policy (PNM) has been improving the access to medicines over the years, once every two years, this relationship is updated, in line with the World Health Organization guidelines. (WHO) on essential medicines in line with human rights.

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