



ISSN: 2230-9926

Available online at <http://www.journalijdr.com>

# IJDR

*International Journal of Development Research*

Vol. 10, Issue, 08, pp. 38997-39002, August, 2020

<https://doi.org/10.37118/ijdr.19606.08.2020>



RESEARCH ARTICLE

OPEN ACCESS

## JUDICIALIZATION OF THE ACCESS TO MEDICINES IN BRAZIL

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### ARTICLE INFO

#### Article History:

Received 04<sup>th</sup> May 2020

Received in revised form

20<sup>th</sup> June 2020

Accepted 19<sup>th</sup> July 2020

Published online 26<sup>th</sup> August 2020

#### Key Words:

Health judicialization. Judicial decisions.

Generics drugs. Pharmaceutical Assistance. Right to health.

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### ABSTRACT

The health judicialization is the social and legal phenomenon of increased lawsuits requesting access to health based on the constitutional projection of this right. The objective of the study was to summarize the results of original articles about the demands profile in the search for medicines through judicial channels in Brazil. It's an integrative review about original articles in the databases Scientific Electronic Library and Virtual Health Library databases, using the combination of descriptors as a search strategy. From the selected articles, it was extracted socio-demographic data (age group, sex), medical-sanitary data (generic name and additional non-medical documents besides the medical prescription used in the request) and political-administrative data (origin of the medical prescription, the drug presence in the official lists and whether it was covered by each component of the Pharmaceutical Assistance blocks). Women aged 50 years old are the biggest claimants of lawsuits pleading the right to health. In the demand for medicines, there is a greater use of the commercial name rather than the generic denomination in the medical prescriptions. Most of the demanded medicines are not in the national, state and / or municipal official lists and among the standardized drugs requested by the courts, these ones are included in the basic and specialized component of Pharmaceutical Assistance. It was not possible to draw a profile for the public or private origin of the medical prescriptions. It is necessary to deepen the studies on drug demands systematizing information and building monitoring indicators that enable the elaboration of effective strategies to improve access to health.

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Citation: *Leila Abou Salha, Marcos Rassi Fernandes, Maria Alves Barbosa, Karoline Ferreira Carvalho and Amanda Sales Camargo.* "Judicialization of the access to medicines in Brazil", *International Journal of Development Research*, 10, (08), 38997-39002.

### INTRODUCTION

The social rights are presented in the article 6<sup>th</sup> of the Brazilian Federal Constitution of 1988, highlighting the right to health (BRASIL, 1988). The drug supply is ensured not only by the Federal Constitution, but also by laws that compound the organization of the Brazilian Health System (SUS), as the Health Organic Law – Law 8.080/1990 (BRASIL, 1990). So, according to it, it's correct to say that the right to access drugs is legitimate. The drugs offer in the Brazilian Health System is organized in three components that compound the financing package of the pharmaceutical assistance, as the basic component, key component and the specialized component (BRASIL, 2004) that are all described in the National Relation of the Essentials Drugs – NRED (RENAME) (MS, 2018).

It contemplates the selection and standardization of these products listed for the disease services or grievances in the public area (BRASIL, 2011). The Executive Authority has the role of formulating and executing the public policies. However, there is omission or non-delivery of this service to the population, resulting in judicial demands of the citizens in order to guarantee the judicial protection of the right to the health access. The increase of the social and legal phenomenon of these claims is named as "judicialization of health" (SANT'ANA *et al.*, 2011). The government excuse to not accomplish its social function, most of the times is based, in the lack of resources and in the close financial dependency to establish the social rights called principle of the possible reserve (COSTA; AMARAL, 2013). There was an exponential growth of the judicial requests for obtaining the medicines,

culminating with difficulties in generating iniquities, difficulties in managing pharmaceutical care and the patient safety (PEPE *et al.*, 2010). Most of these demands to get the medicines are inappropriate, therapeutic indication without established evidences and absence with no official records (PEPE *et al.*, 2010; NETO, 2015). It is relevant to understand the judicialization phenomenon through the survey of lawsuit aspects as a way to mitigate the phenomenon. The objective of this study was to summarize the results of some original articles about the claimants' profile in the drugs search by judicial ways.

## METHODS

An integrative review of the literature about the drug judicialization was carried out, from April to June of 2020 in the indexed databases of Scientific Electronic Library Online (SciELO), Virtual Library in Health (BVS) and CAPES site. The guiding question of this study was "What are the claimants profile in the drugs judicialization in Brazil?" The search strategy consisted in the use of descriptors in Health Science (DeCS) and Medical Subject Heading (MeSH) in a combined way: Health judicialization AND drugs; Judicial decisions AND drugs; Pharmaceutical care AND health judicialization; Judicial decisions AND drugs AND health rights. The inclusion criteria were full texts available in scientific paper layout; published in the last years (2013 to 2020); in Portuguese or English; and Brazilian drugs lawsuit. The exclusion criteria were extrajudicial demands papers (non-judicial process); processes that refer exclusively to demands for health products that are not specifically about drugs and studies uniquely qualitative, dissertations and thesis. Initially, some titles and summaries were read and on them the eligibility criteria and guiding question were applied. Afterwards, a single researcher selected some articles and a fully reading of them was done. The following relevant data was collected: age group (in living years); sex of the drug claimants (male/female); use of the generic name (yes/no); medical prescription in the judicial demands (with prescription / without prescription); origin of medical prescription (public or private service); the drug presence in the official lists (yes/no) and drug covered in components of the Pharmaceutical Assistance blocks (basic/specialized/strategic). This data was extracted according to the indicators assessment manual and the monitoring of drugs judicial demands of Public Health National School / FIOCRUZ (PEPE *et al.*, 2011).

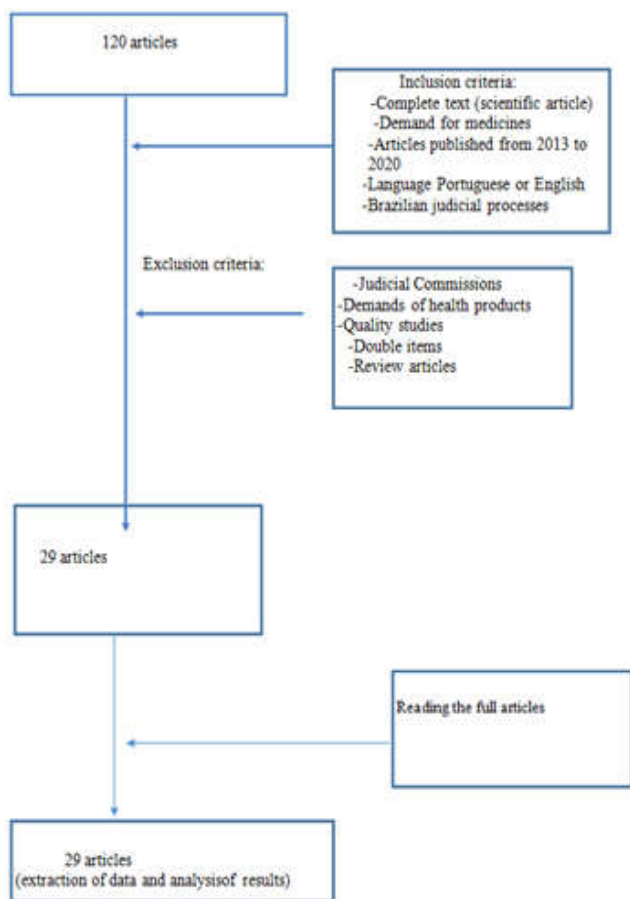
## RESULTS

It was found 120 studies using search strategies adopted in the databases. After reading the titles and abstracts applying the eligibility criteria, 29 articles were selected for a full reading, data extraction and results analysis (Figure 1). From the 29 articles selected, only three addressed the claimant's age group. The average age of the claimants was 53.4 (NUNES; RAMOS JUNIOR, 2016) and 56 years old (NISHIRA *et al.*, 2017) In another study, individuals were 60 years old and over (PICOLINI *et al.*, 2016). Few studies have addressed the gender variable, and in these, most of the requests were made by women (NUNES; RAMOS JUNIOR, 2016; NISHIRA *et al.*, 2017; BOING *et al.*, 2013; CABRAL; REZENDE, 2014) and only one by men (DINIZ *et al.*, 2014). Five studies addressed the request using the generic name of the drug, and the frequency was 48.8% (PEREIRA; PEPE, 2014), 40.2% (LOPES, 2014), 48.9% (PICOLINI *et al.*, 2016), 34%

(NISHIRA *et al.*, 2017) and 28.8% (LEITAO *et al.*, 2016). Only one study addressed the presence of another document besides the medical prescription to support the judicial request (BARRETO *et al.*, 2013). Regarding the origin of the health service, five studies addressed this variable, and in three of them, the most part was from public origin (NUNES; RAMOS JUNIOR, 2016; DINIZ *et al.*, 2014; BARRETO *et al.*, 2013) and two from private origin (CABRAL; REZENDE, 2014; SANTOS *et al.*, 2017). Only eleven publications showed requests for drugs in official lists, being 22 to 61% (BARRETO *et al.*, 2013); 12.3% (PEREIRA; PEPE, 2014); 29% (BOING *et al.*, 2013); 43.61% (CABRAL; REZENDE, 2014); less than 50% (PINTO; CASTRO, 2015), 37.95% (MAGALHAES, 2015); 33% (COSTA, 2016); 31.2% (NISHIRA *et al.*, 2017); 23.7% (LEITAO *et al.*, 2016); 2.8% (SANTOS *et al.*, 2017) and 50.4% (PAIM *et al.*, 2017). Most of these drugs were part of a specialized component of pharmaceutical assistance (PEREIRA; PEPE, 2014; PINTO; CASTRO, 2015; PAIM *et al.*, 2017), instead of the basic component (BARRETO *et al.*, 2013; PINTO; CASTRO, 2015; PAIM *et al.*, 2017) and strategic component (PAIM *et al.*, 2017).

## DISCUSSION

In 29 articles published from 2013 to 2017 with a time range of 18 years, varying from 1998 to 2016 and 11,090 processes, it can be stated that women over 50 years old are the largest group of drug claimants. The identification of sociodemographic characteristics makes it possible to recognize characteristics of population groups seeking justice. Data from IBGE (BRASIL, 2010) and some other studies (LEVORATO, 2014; DINIZ *et al.*, 2018; PINHEIRO *et al.*, 2002; RIBEIRO, 2005; TRAVASSOS *et al.*, 2002) showed the association between female sex and the search for health care services in the order of 1.9 to 2.43 times compared with male sex. In Brazil, it is correct to say that this predominant use is made by the female sex, and as they are the majority, it establishes them as the determinants for the consumption of health services (RIBEIRO, 2005; TRAVASSOS *et al.*, 2002). Furthermore, it can be observed that women constitute the majority of formal and informal caregivers of patients what could suggest the suit in favor of this group (DINIZ *et al.*, 2018; OLIVEIRA; D'ELBOUX, 2012). Regarding the use of medicines generic name in medical prescriptions used in legal demands, most of the cases presented a description of the medicines with the commercial name. It is important to emphasize the impossibility of not using this denomination in lawsuits, in order to meet the legal precepts established by Law no. 9,787 / 99, which provides that the purchase of medicines under SUS must adopt such classification (BRASIL, 1999). The imposition of a commercial name enforces to the Judiciary the acquisition of a specific brand, violating the principle of separation of powers because the Executive Authority has to purchase medication, which may not have demonstrated suitable benefits to the treatment (ALVES, 2015). Law no. 12,401 / 2011 establishes the necessity of the prescriptions being accordingly with the therapeutic guidelines defined in a clinical protocol for the disease or health problem (BRASIL, 2011), which frustrates the principle of bidding for raising public expenditures, making the acquisitions unreasonable and inequality for the bidders. It is highlighted the possibility of investment in the prescribing professional by the drug manufacturer to favor a particular purchase of a specific drug that is not offered by



**Figure 1. Flowchart of the study search strategy**

SUS (KARNIKOWSKI *et al.*, 2017). Taking into consideration the analysis of price changes for the same drug, there is an increase in the costs of pharmaceutical assistance, and although the use of the generic name in the prescriptions promotes the rational use of medicines, stimulates the purchase of cheaper medicines and encourages the suitable use of public resources (CATANHEIDE *et al.*, 2016). The additional documents other than medical prescriptions express the use of any document as exams and clinical reports that compound the lawsuit. These ones can help the judge to take a decision about the request approval or not. There are few studies related to this data. The medical report has a great importance to help taking the decision and also the lack of the additional documents (BARRETO *et al.*, 2013). Besides that, there is some difficulty in the access to the medical prescription and some other documents what could help the lawsuits. The lack of medical prescription combined to the prevalence of the ones which do not use the generic name or without other minimum legal precepts, as it is showed in some studies, demonstrates that judges do not comply with these formal and legal requirements for the medicines supply under SUS (PEREIRA; PEPE, 2014; BARRETO *et al.*, 2013). The use of other documents could also bring some benefits to enhance a better diagnosis and, consequently, an approach to the Medicine Based in Evidences, a scientific practice that SUS has as its basis (BRASIL, 1990). Regarding to the service nature, from the five studies that presented this data, three of them had some requests from the public service. However, these three studies had methods that could not be compared to the others. The prescription that comes from private origin can be placed to no hurt the principle of equity, once the medicines are provided to people who do not use the public health system

and do not depend of the free supply of medicines (CABRAL; REZENDE, 2014). Furthermore, it is discussed if SUS could assist private prescriptions to disobey what is envisaged in the Art.28 of the Decree n.7.508/11 (BRASIL, 2011) that says: the access to the pharmaceutical assistance occurs by the assisted user through actions and health services of SUS; the medicine is prescribed by health professionals, in the regular exercise of their duties in SUS; the prescription is accordingly to RENAME and the Clinical Protocol/Treatment Guidelines related to additional specific medicines state, district or municipal. Related to the constant medicines in official lists, it was observed that most of the defendants were not in any official list, so they were not standardized and the use was not evaluated by technical committee. In this regard, it can be stated that, in the studies assessed, these lists were not checked and/or taken into consideration in the court decision for medicines. It can be justified by professional's lack of awareness related to the official lists content and for not the adhering of forcing the inclusion of medicines in SUS by manufacturer, using health professionals or users (BRASIL, 1999).

The negative effect of the judicialization involves topics like dispensing of non-standard medicines; use off label; rejection of the existing therapeutic alternative in SUS without scientific basis; and disrespect to the guidelines of the safe and rational use of medicines from National Policy of Medicines and National Policy of Pharmaceutical Assistance (BRASIL, 2011). It can also be mentioned the management problems of the pharmaceutical assistance as a barrier to the access, delay in the assessment of administrative requests and obsolescence of the Clinical Protocols and Treatment Guidelines of SUS (KARNIKOWSKI *et al.*, 2017). These considerations above contrast to the positive aspects of the situation, that would be the identification of failures in pharmaceutical assistance management, with difficulty in accessing official lists; failure in the inclusion of new medicines to the current lists and the Executive's omission to guarantee the provision of such assistance already foreseen in public policies (CATANHEIDE *et al.*, 2016). Paimet *al.* reported 7.6% of drugs in the basic component and 11.4% in the specialized component of the official lists (PAIMet *al.*, 2017).

In the other studies, the drugs present in each component of the Pharmaceutical Assistance were addressed, some of which pointed to a higher demand for those of the basic component (BARRETO *et al.*, 2013; MAGALHAES, 2015) and the others for a specialized component (PEREIRA; PEPE, 2014; PAIMet *al.*, 2017). This difference was not possible to be explained. In response to the crescent judicialization demands, the National Council of Justice pronounced its position number 31, March 31, 2010 (CNJ, 2018), recommending that the Courts of Justice and the Federal Regional Courts conclude agreements to have some technical support from doctors and pharmacists in the sense to assist magistrates in the clinical issues of health-related actions (BRASIL, 2011). This recommendation is extremely valid as it enables the evaluation of data such as those presented in this study to support judges' decisions in granting requests for medicines in a more reasonable way by meeting objective criteria based on scientific evidence that will compose reproducible and usable databases in other states of the federation. Regarding to the limitation of the study, the selected articles addressed a questionnaire (LOPES, 2014; MAGALHAES, 2015), two (NUNES; RAMOS JUNIOR, 2016; BOING *et al.*, 2013; DINIZ *et al.*, 2014;

Chart 1. Summary of Data from the Surveyed Articles

Yearofpublication	Temporal cutofstudies	Numbersof Processes	Data basis	Locals	Average Ages	Sex	Genericname	Documents/servicetype	Officiallists	ComponentPA	
Mariotto. et al.	2013	2008- 2009	1	JP	MT	-	-	-	-	-	
Medeiros et al.	2013	2006-2010	195	JP	União	-	-	-	--	-	
Barreto et al.	2013	2006-2010	228	JP	BA	-	-	Withoutprescription / Public	22. 3% a 61%	Basic	
Pereira et al.	2013	2009	694	JP	PR	-	-	48. 8%	12.3%	Specialized	
Ramos; Ferreira	2013	2010	212	JP	MG	-	-	-	-	-	
Boing et al.	2013	2000-2006	2580	JP	SC	-	Female	-	29%	-	
Diniz et al.	2013	2005-2010	385	JP	DF	-	Male	Public (85%)	-	-	
Travassos et al.	2013	2009	558	Acórdão	PE, RS e MG	-	-	-	-	-	
Santos, R.	2014	2008-2009	34	JP	MT	-	-	-	-	-	
Lopes,LC	2014	2004-2010	203	JP	SP	-	-	40. 2%	-	-	
Carvalho, M.	2014	-	10	interview	AM	-	-	-	-	-	
Cabral et al.	2014	2009-2012	87	JP	SP	-	Female	Private (70,1%)	43. 61%	-	
Trevisan, L.	2014	2001-2010	19	JP	RS	-	-	-	-	-	
Sopelsa M.	2014	2014	1528	SDM	RS	-	-	-	-	-	
Silva Junior ;Dias	2015	2014	67	interview	CE	-	-	-	-	-	
Honorato, S.	2015	2010-2012	359	Acórdão	DF	-	-	-	-	-	
Lisboa, E.	2015	2010-2013	154	JP	BA	-	-	-	-	-	
Pinto et al.	2015	2008-2012	771	JP	MS	-	-	-	Lessthan 50%	6 a 42% Basic 6 a 25% specialized	
Magalhães,ASF	2015	2014	121	JP	DF	-	-	-	37. 95%	-	
Zago, B	2016	2007-2012	175	JP	SC	-	-	-	-	-	
	2016	1998-2012	965	JP	CE	53. 4	Female	Public (76,3%)	-	-	
	2016	2007-2015	17	JP	Brasil	-	-	-	33%	-	
	2016	-	107	JP	SP	60	Female	48,9%	31. 2%	-	
	2016	2009-2010	58	JP	PB	-	-	28,8%	23. 7%	-	
	2017	2014-2016	244	JP	DF	-	-	-	-	-	
	2017	2014	347	JP	PR	56	-	34%	-	-	
	2017	2004-2013	636	JP	SP	-	-	Private (71, 9%)	2. 8%	-	
	Yearofpublication	Temporal cutofstudies	Numbersof Processes	Data basis	Locals	Average Ages	Sex	Genericname	Documents /servicetype	Officiallists	Component PA
	2017	2004-2015	186	JP	RS	-	-	-	-	50.4%	7,6% (Basic) 11,4% (specialized)
	2017	2010-2013	149	JP	BA	-	-	-	-	-	-

Legend: - no dates; PA: pharmaceutical assistance; JP: judicial process; SDM: medicines distributions systems; Acórdão: judicial process second instances; SP: São Paulo state; AM: Amazonas state; RS: Rio Grande do Sul state; PE: Pernambuco state; MG: Minas Gerais state; CE: Ceará state; DF: Distrito Federal; BA: Bahia state; MS: Mato Grosso do Sul state; SC: Santa Catarina state; PB: Paraíba state; PR: Paraná state.

LEITAO *et al.*, 2016; SANTOS *et al.*, 2017; PINTO; CASTRO, 2015; PAIME *et al.*, 2017), three (CABRAL; REZENDE, 2014; PEREIRA; PEPE, 2014; BARRETO *et al.*, 2016) or four (NISHIRA; RAMOS JUNIOR, 2016) criteria in the Manual of Indicators for Evaluation and Monitoring the Drug Claims of National School of Public Health / FIOCRUZ (PEPE *et al.*, 2011), however, none of them considered all of them, and yet, 13 articles (MARIOTTO *et al.*, 2013; MEDEIROS *et al.*, 2013; RAMOS; FERREIRA, 2013; SANTOS *et al.*, 2014; CARVALHO; LEITE, 2014; TREVISAN, 2014; SOPELSA *et al.*, 2017; SILVA JUNIOR; DIAS, 2015; HONORATO, 2015; LISBOA, 2015; ZAGO *et al.*, 2016; SILVA *et al.*, 2017; LISBOA; SOUZA, 2017) did not mention any of the criteria, which impaired the comparative discussion. The aspects related to the health judicialization are multifactorial and leads to diverse reflections. This article has restricted itself to analyze characteristics of demands described in recent publications and discuss about them, and it is recommended new studies to keep the problem's discussion.

## Conclusion

Women aged 50 and over are the largest group of claimants of lawsuits claiming health care rights. In the demand for medicines, the commercial name is much more used than the generic denomination in the medical prescriptions. Most of the drugs demanded are not in national, state and / or municipal official lists and among the standardized drugs requested by the courts, these are included in the basic and specialized component of Pharmaceutical Assistance. Judicialization is a legitimate and necessary phenomenon due to the State's omission to provide public policies for pharmaceutical assistance. However, the concern is highlighted because of the scarcity of public resources to meet the established programs. It is necessary to systematize information about the lawsuits constructing monitoring indicators to supervise and compare in the towns / cities of the country, what will enable the construction of effective strategies to improve the access to health and change the current scenario.

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