

## HEALTH JUDICIALIZATION IN A LARGE CITY

### JUDICIALIZAÇÃO NA SAÚDE EM MUNICÍPIO DE GRANDE PORTE

### JUDICIALIZACIÓN DE LA SALUD EN UN GRAN MUNICIPIO

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## ABSTRACT

**Introduction:** judicialization as a phenomenon of guaranteeing the right to health is a question with a growing discussion in Brazil, due to the constitutional definition of health in the country, which contemplates integrality. **Objective:** to characterize the processes of health judicialization in a large city. **Method:** descriptive, quantitative and documental study conducted in the 1<sup>st</sup> and 2<sup>nd</sup> Court of the *Fazenda Pública da Comarca de Londrina – Paraná*. The information was collected in the electronic process system of the Paraná Court. **Results:** 706 processes were identified, with the majority (51.2%) of the actions imposed by women, over 60 years old (47.5%), with their origin via public service (71.7%) and represented by private lawyers (55.3%). The most demanded object were medicines (88.1%), 80.1% of which not present in the *Relação Nacional de Medicamentos Essenciais*. During the data collection period, the majority (85.5%) of the processes was in course and, of these, 36.5% had more than 900 days. The outcome of the archived processes was judged well founded in 60.8% and unfounded in 17.6%. The total amount spent on judicialization during the study period was more than R\$ 55,000,000.00. **Conclusion:** to reduce costs and the amount of lawsuits, public health policies should be reviewed in order to include the largest number of medicines in health services lists, facilitating the access of these products to users of *Sistema Único de Saúde (SUS)*. New research is suggested to investigate the reason of medical prescription of non-standardized medicines.

**Keywords:** Health's Judicialization; Judicial Decisions; Health; Right to Health.

## RESUMO

**Introdução:** a judicialização como fenômeno de garantia do direito à saúde é uma questão com crescente discussão no Brasil, devido à definição constitucional de saúde no país, que contempla a integralidade. **Objetivo:** caracterizar os processos de judicialização na saúde em município de grande porte. **Método:** estudo descritivo, quantitativo e documental realizado na 1ª e 2ª Varas da Fazenda Pública da Comarca de Londrina - Paraná. As informações foram coletadas no sistema de processo eletrônico do Judiciário do Paraná. **Resultados:** foram identificados 706 processos, sendo que a maioria (51,2%) das ações foi impetrada por mulheres, acima de 60 anos (47,5%), com origem das prescrições via serviço público (71,7%) e representadas por advogados particulares (55,3%). O bem requerido de maior demanda foram os medicamentos (88,1%), sendo que 80,1% não estavam presentes na Relação Nacional de Medicamentos Essenciais. No período da coleta de dados, a maioria (85,5%) dos processos encontrava-se em tramitação e, destes, 36,5% tinham mais de 900 dias. O desfecho dos processos arquivados foi julgado procedente em 60,8% e improcedente em 17,6%. O valor total gasto com judicialização no período estudado foi acima de R\$ 55.000.000,00. **Conclusão:** para reduzir os custos e a quantidade dos processos judiciais, as políticas públicas de saúde devem ser revistas com o intuito de incluir o maior número de medicamentos nas listas dos serviços de saúde, facilitando o acesso desses produtos aos usuários do Sistema Único de Saúde. Sugerem-se novas pesquisas para investigar o motivo da prescrição médica por medicamentos não padronizados. **Palavras-chave:** Judicialização da Saúde; Decisões Judiciais; Saúde; Direito à Saúde.

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## RESUMEN

**Introducción:** la judicialización como un fenómeno para garantizar el derecho a la salud es un tema de creciente discusión en Brasil debido a la definición constitucional de salud en el país, que incluye la integralidad. **Objetivo:** caracterizar los procesos de judicialización de la salud en una gran ciudad. **Método:** estudio descriptivo, cuantitativo y documental realizado en los 1º y 2º Distritos Judiciales de Londrina – Paraná. La información se recopiló en el sistema de proceso electrónico del Poder Judicial de Paraná. **Resultados:** se identificaron 706 casos. La mayoría (51,2%) de las demandas fueron presentadas por mujeres mayores de 60 años (47,5%), originadas por recetas médicas del servicio público (71,7%) y representadas por abogados particulares (55,3%). El activo más demandado fueron los medicamentos (88,1%), 80,1% de ellos no constaban en la Lista Nacional de Medicamentos Esenciales. Durante el período de recogida de datos, la mayoría (85,5%) era de casos en tramitación y de estos, el 36,5% desde hacía más de 900 días. El resultado de las demandas se confirmó en 60,8% de los casos y se declaró improcedente en 17,6%. El monto total en judicialización en el período estudiado superó los R \$ 55.000.000,00. **Conclusión:** para reducir los costos y la cantidad de demandas, las políticas de salud pública deben revisarse para incluir la mayor cantidad de medicamentos en las listas de servicios de salud, facilitando el acceso de estos productos a los usuarios del Sistema Único de Salud. Se sugiere investigación adicional para averiguar el motivo de la prescripción de medicamentos no estándar.

**Palabras clave:** Judicialización de la Salud; Decisiones Judiciales; Salud; Derecho a la Salud.

## INTRODUCTION

In Brazil, health is a fundamental right of citizens, guaranteed by the Brazilian Federal Constitution (*Constituição da República Federativa*) institutionally of 1988, which created the Unified Health System (*Sistema Único de Saúde-SUS*), which is composed of a set of health actions and services. It is a regionalized and hierarchized network whose constitutional principles include universality, integrality of care and equality. The three spheres of Brazilian government (federal, state and municipal) share the responsibility of guaranteeing the right to health.<sup>1</sup> When health service managers fail to guarantee the right of the users, they seek their rights via "health judicialization".

Health judicialization is the cost of medical procedures or medicines by judicial approach. This theme is of high relevance for public administration, since the number of lawsuits are determined to the public manager to grant the health treatment is high, resulting in expenditure for the public sector.<sup>2</sup>

The growth of judicial actions, causes unpredictable expenditures on municipal, state and federal budgets, and enormous expenditures on the SUS. In different Brazilian states studies have been conducted with the objective of understanding the phenomenon of judicialization, identifying the profile of the processes, the interferences on the causes and characterizing the various aspects involved to identify

alternatives that can solve the problems.<sup>3-5</sup> The result of one of these studies demonstrated that the state of Ceará has 8,344 health lawsuits, being considered the 4<sup>th</sup> largest number of processes in the country.<sup>4</sup>

A research conducted in *São João da Boa Vista-SP* analyzed judicial actions for access to medicines, identifying that the average expenditure per lawsuit was R\$ 5,994.95 in 2010 and R \$25,577.80 in 2012. These actions have important budgetary consequences, resulting in high and unscheduled expenditures to health managers.<sup>6</sup> There is a significant increase in drug expenditures in Brazil, which rose from R \$14.3 billion in 2010 to almost R \$20 billion in 2015 (40% growth).<sup>7</sup>

The motivation to accomplish this research was based on the exponential increase in expenditures on health judicialization in recent years in the city studied. According to a report presented at a meeting of the Municipal Health Council (*Conselho Municipal de Saúde*) of Londrina, there was an expense of 1.879 billion with judicialization in four years (2013-2016), with an increase of 38% of expenditure between 2013 and 2016.8.

The aim of this study is to characterize the processes of health judicialization in a large city.

## METHODS

This is a descriptive research of quantitative approach of documental type, held in the 1<sup>st</sup> and 2<sup>nd</sup> Courts of the *Fazenda Pública da Comarca* of Londrina-PR.

In the city studied there are 10 civil Courts and two poles of Public Treasury. The civil authorities have the competence to prosecute and judge bankruptcies and causes relating to the judicial or extrajudicial recovery of entrepreneur or business companies. The courts of the public treasury process and judge the causes in which the state, municipality, autarchies, mixed economy societies, public companies or foundations interested in the conditions of authors, defendants or assistants.<sup>9</sup> Thus, for data collection, the research was carried out in the 1<sup>st</sup> and 2<sup>nd</sup> Court of the *Fazenda Pública da Comarca* of Londrina - Paraná, where can be found judicial actions against the municipalities, state, union and local authorities.

All cases included filed between 2011 and 2017 were included, inserted in the electronic process system of the Judiciary of Paraná (PROJUDI), a computerized system that records the entire judicial procedure in electronic media, replacing the paper file registration. Labor and veterinary actions were excluded.

For data collection, the judges of the 1st and 2nd Courts of the Public Treasury of Londrina received a request of the Coordination of the Nursing Graduate Program at *Universidade Estadual de Londrina*, to obtain authorization of access to health judicialization processes in the city studied. After the

judges' authorization, the secretaries of both Courts carried out a search in the register referring to the lawsuits in health, to generate a list with the processes numbers.

The participation of an attorney was requested to access the website of the electronic process of the judiciary of *Paraná* (PROJUDI), to obtain the research data in the processes released. This lawyer, through his own password, accessed the PROJUDI website to obtain the search data.

The variables of analysis were: gender (male and female); age group (under 20 years old, from 21 to 40 years old, from 41 to 50 years old, from 51 to 60 years old and more than 60 years old); origin of the prescription (public and private); legal representation (public prosecutor and private lawyer); required goods (medicine, material and input, surgical procedure, medical consultation, examinations, among others); registration at the *Agência Nacional de Vigilância Sanitária* (ANVISA) and in the *Relação Nacional de Medicamentos Essenciais* (RENAME); process identification (in process and filed); processing time (100 to 300 days, 301 to 500 days, 501 to 700 days, 701 to 900 days and above 900 days); outcome of the filed processes (founded, unfounded, withdrawal or death of the author); reason for the unfounded judgment (judicial incompetence, not proving the need for the requested product, prescription by a physician not linked to SUS, duplicity of actions and decay of the process); and value spent on judicialization.

The medicines were classified by the Anatomical Therapeutic Chemical (ATC), which, from 1996, was recognized by the World Health Organization as an international standard for drug use studies. Active substances are classified into a five-level hierarchy.<sup>10</sup> In this study, the medicines were classified by therapeutic group.

The data were stored in a Google Docs spreadsheet and analyzed by descriptive statistics, using the Statistical Package for Social Sciences 22.0 (SPSS 22.0) program.

The study was approved by the Ethics and Research Committee of the *Universidade Estadual de Londrina-PR*, under the number CAAE: 75955417.1.0000.5231.

## RESULTS

We identified 945 processes, of which we excluded 155 because they were duplicated. In addition, 83 were labor actions and a veterinary action, totaling 706 actions of health judicialization eligible for the study.

Some processes presented collective actions (n=21), that is, several individuals in a single action, totaling 775 people who demanded some kind of judicial action. In relation to the characterization of the applicants, female gender (51.2%) and age group over 60 years old (47.5%) predominated. The origin of the most frequent medical prescription was public network (71.7%) and legal representation by private lawyers (55.3%) (Table 1).

Table 1 - Characterization of lawsuits applicants. *Londrina/PR*, 2011 to 2017

Variable	n	%
<b>Sex (n= 775)</b>		
Female	397	51.2
Male	378	48.8
<b>Age group (years old, n= 775)</b>		
< 20 years old	12	1.5
21 - 40 years old	133	17.2
41 - 50 years old	109	14.1
51 - 60 years old	148	19.1
More than 60 years old	368	47.5
Not informed	5	0.6
<b>Origin of prescription (n= 775)</b>		
Public network	556	71.7
Private network	149	19.3
Not informed	70	9.0
<b>Legal representation (n= 706)</b>		
Public Prosecution	316	44.7
Private attorney	390	55.3

\*n refers to the number of legal proceedings perpetrators.

In the required demand, we observe in Table 2 that the highest number of lawsuits was for medicines (88.1%). The length of processing of these processes was mostly over 900 days (30.0%) and 14.3% were filed.

Table 2 - Required demand type. *Londrina/PR*, 2011to 2017

B Required good	n	%
Medicines	622	88.1
Materials and inputs	21	3.0
Surgical procedure	16	2.2
Medical consultation	12	1.7
Exams	12	1.7
Others	23	3.3
<b>Total</b>	<b>706</b>	<b>100</b>

As for the medicines required, the results showed that 99.2% were registered with the *Agência Nacional de Vigilância Sanitária* (ANVISA) and 80.1% were not in the Essential Medicines Association National (*Relação Nacional de Medicamentos Essenciais*- RENAME), current at the time the processes were analyzed (2017).

Moreover, according to the ATC classification, it was found that the most frequent therapeutic group was "antineoplastic agents", with 41.0%, followed by "endocrine therap" with 8.4% (Table 3).

Table 3 - Classification of medicines according to therapeutic group of Anatomical Therapeutic Chemical. *Londrina/PR, 2011 to 2017*

ATC	Therapeutic group	n	%
L01	Antineoplastic agents	295	41.0
L02	Endocrine therapy	60	8.4
L04	Immunosuppressants	55	7.7
S01	Ophthalmologic	47	6.6
B01	Antithrombotics	27	3.8
N03	Antiepileptics	16	2.2
J05	Antivirus for systemic use	16	2.2
M05	Drugs for the treatment of bone diseases	15	2.1
H05	Calcium homeostasis	13	1.8
A10	Medicines used in diabetes	13	1.8
N05	Psycholeptics	12	1.7
N06	Psychoanaleptics	11	1.5
H01	Pituitary and hypothalamus hormones and analogues	8	1.1
C10	Lipid modification agents	7	1.0
C02K	Antihypertensive	6	0.8
	Other therapeutic groups	117	16.3
	<b>Total</b>	<b>718</b>	<b>100</b>

Among the most requested antineoplastic agents, the most demanding was bevacizumab, with 23.0% (not present in RENAME), followed by rituximab with 14.2% (present in RENAME), trastuzumab (9.6%) and cetuximab (7.5%) (both not present in RENAME).

Regarding the time of process demand, it was observed that most of the processes were in course during the data collection period (2017) (85.6%), and 220 (36.5%) had more than 900 days of processing time.

Some of the reasons for unfounded judgment were judicial incompetence, six (33.4%); four (22.2%) have not proven the need for the medicine requested; in one (5.5%) the perpetrator had a private health insurance and the judge understood that he should appeal to them (Table 4).

Table 4 - Identification of processes for processing time, outcome of the filed cases and reason for unfounded trial. *Londrina/PR, 2011 to 2017*

Variable	n	%
<b>Process identification</b>		
In course	604	85.5
Filed	102	14.5
<b>Processing time</b>		
100 to 300 days	76	12.6
301 to 500 days	105	17.4
501 to 700 days	106	17.5
701 to 900 days	97	16.0

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Table 4 - Identification of processes for processing time, outcome of the filed cases and reason for unfounded trial. *Londrina/PR, 2011 to 2017*

Variable	n	%
<b>Processing time</b>		
More than 900 days	220	36.5
<b>Outcome of the filed cases</b>		
Founded	62	60.8
Unfounded	18	17.6
Perpetrator withdrawal	12	11.8
Perpetrator death	10	9.8
<b>Reason for unfounded trial</b>		
Judicial incompetence	6	33.4
Did not prove the need for the requested medicine	4	22.2
Prescription by doctor not linked to SUS	3	16.6
Duplicity of legal action in another Court	2	11.1
Process decay	2	11.1

The expenses with health judicialization in legal actions for medicines (R \$52,413,180.03) and treatment with hyperbaric oxygen therapy (R \$1,046,472.34), are shown in Table 5. It is noteworthy that the values registered in the processes often did not correspond to the real value of the action, because when registering the value of each action the lawyer entered only the amount spent on the procedural costs.

Table 5 - Amount spent on health judicialization. *Londrina/PR, 2011 to 2017*

Type of action required	Amount spent (R\$)	%	Average
Medicines	52.413.180.03	94.4	82.665.00
Hyperbaric oxygen therapy	1.046.472.34	1.8	149.496.00
Materials and inputs	960.440.60	1.7	47.972.00
Surgical procedure	617.546.90	1.2	41.169.79
Medical consultation	304.100.00	0.6	25.341.67
Intensive care unit bed	104.000.00	0.2	34.000.00
Others	44.650.45	0.1	3.891.00

## DISCUSSION

The results of the research showed several types of health-related legal actions, in which the greater request was medicines judicialization, followed by materials and inputs, surgical procedures and others. In a study on health judicialization in the state of *Mato Grosso* between the years 2011 and 2012, the most frequent request were for surgeries or procedures and beds, followed by medicines.<sup>11</sup> It is noteworthy that the state of *Mato Grosso* is outside the ideal number of hospital beds recommended by the World Health Organization for every

thousand inhabitants, which generates the various lawsuits requiring beds, as a consequence of the lack of investment to increase their amount in the state.<sup>11</sup>

The results of this study corroborate others that demonstrated that most of the medicines requested had ANVISA register<sup>13,12</sup>. This information is relevant, as the *Conselho Nacional de Justiça* (CNIJ) recommend the Courts to adopt measures that better subsidize the magistrates and ensure greater efficiency in the solution of judicial demands related to health care, such as the requirement to approve the inputs requested by the ANVISA. This measures would avoid that products with unproven results or that can be harmful are provided to the users.<sup>14</sup>

We observed that about 80% of the medicines requested were not present in the RENAME. On the contrary, a study conducted in 2005 on legal actions related to medicines access in *São Paulo*-SP, found that 62% of the medicines required were part of the SUS drug lists, indicating that the prescriber or the applicant may not know whether these medicines were available or not, considering that most of the prescriptions were from SUS services.<sup>15</sup>

Regarding the types of medicines requested, antineoplastic agents were more frequently found, among them the rituximab, present in the RENAME. In a research conducted in the state of *Paraíba* with the objective of describing the medical-scientific and sanitary aspects of judicial orders for medicines supply, antineoplastic rituximab was the most requested.<sup>16</sup> The fact that some of the medicines requested belong to the lists of medicines provided by SUS may indicate the lack of these medicines in drugstores due to failures in pharmaceutical care management and prescribers' little knowledge about the supply rules of these items by SUS.

Also about antineoplastic agents, the most requested in this study was bevacizumab, not present in RENAME. In a research conducted in *Minas Gerais* with the objective of analyzing the possible interference of the pharmaceutical industry in medicines prescriptions, it was found that the pharmaceutical industry used strategies to convince physicians and/or patients for the use of medicines that are not standardized in the SUS yet.<sup>17</sup> Prescriptions not supported by diagnosis and therapeutic indications established in clinical protocols and therapeutic guidelines, concentrations and non-standardized pharmaceutical forms, contribute to increase legal demands for non-standardized technologies.

It is assumed that the predominance of legal actions for antineoplastic agents demonstrates the need to discuss public policies that meet the therapeutic needs of the population, based on the changes generated with population growth and increase in chronic-degenerative diseases.

This study found a predominance in medical prescriptions from the public network, as also observed in the state of *Ceará*.<sup>4</sup>

On the contrary, researches carried out in *Minas Gerais* and *São João da Boa Vista*-SP found that most of the prescriptions came from physicians of the private sector, which may indicate a "partnership" between these professionals and the laboratory manufacturer of the drug aiming at its standardization.<sup>6,18</sup>

Even evidencing in this research that most of the origin of prescriptions comes from consultations in SUS, there is a hegemony in the legal representation by private lawyers, cases also observed in other states of the country.<sup>15,18-20</sup> These results may indicate that, even using the public health system, people who appeal to the judiciary have better financial conditions and can assume procedural expenses.

Most of the processes analyzed during the data collection period of this study were in course for more than 900 days. This long time may indicate more costs for the public health system and be harmful to the user in the waiting time. There is a need to conduct studies that address the length of the processes and the costs involved during the waiting time for the judicial decision, so that they can reduce the costs of the health judicialization and provide a nimbler response to the user.

In this study and in other researches, the value spent with medicine legal actions draws attention. In 2006, R\$ 21 million were spent with the fulfillment of judicial decisions for drugs demand in the state of *Santa Catarina*.<sup>21</sup> In another study carried out in that same state, in 13 municipalities with low population density, the expenses were a little more than R\$1 million of expenses with judicial lawsuits.<sup>2</sup> A study carried out in *Distrito Federal*, analyzed the expenses with non-standardized and judicialized medicines in the SUS, resulting in a total spending of about R\$ 43 million.<sup>5</sup>

The high costs of medicines judicialization may be due to the non-standardization of medicines in the SUS, having significant budgetary implications for the system, since the judicial determinations for drug distribution causes high expenditures that are not programmed by health managers.

This study was the lack of enough data to trace the socioeconomic profile of the applicants, since legal actions did not usually have data on school level, place of birth, profession and income. Another limitation was about the values found in each action, because in many processes the actual values of the cost of the action were not recorded, making it impossible to know the total value spent in the period studied.

## CONCLUSION

The results showed that most of the actions were started by women over 60 years old, with the origin of prescriptions via public service and represented by private lawyers. The most required demand were for medicines, most of which are registered in ANVISA and were not present in the RENAME. The most frequent group was "antineoplastic agents".



During the data collection period, most of the processes were in course for more than 900 days. The outcome of the processes was founded in 60.8% and unfounded in 17.6%. The total amount spent on judicialization during the study period was above R\$ 55,000,000.00.

Although the analysis of the expenses with the judicialization did not allow to find the real value of each legal action, the data allowed to identify high cost with the processes of the period studied. The results showed that health judicialization can indicate that investments in the health sector have been insufficient to meet the demands of the population.

We suggest the reformulation of the national drug policy to be enlarged, allowing the SUS acquisition of non-standardized drugs. We also recommended to carry out further research identify the reasons why physicians prescribe medicines not standardized in RENAME.

We also proposed the insertion of a multidisciplinary team capable to advise the judges in the verification of scientific evidence of the treatments requested in the lawsuits, avoiding the prescription of medicines or procedures without proven evidence, in order to reduce the amount of legal actions and high health expenditures.

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