

# Judicialization of health: lawsuits for access to medicines in Uruguaiiana-RS

Mariana Ilha Ziolkowski<sup>1</sup>, Graziela Scheuer Gomes<sup>2</sup>, Eduarda Martini Piegas<sup>1</sup>, Alcides José Parisotto<sup>1</sup>, Raqueli Altamiranda Bittencourt<sup>2</sup>, Sandra Elisa Haas<sup>1,2</sup>

<sup>1</sup>Programa de Pós-Graduação em Ciências Farmacêuticas, Universidade Federal do Pampa (UNIPAMPA) - Uruguaiiana (RS), Brazil

<sup>2</sup>Faculdade de Farmácia, UNIPAMPA - Uruguaiiana (RS), Brazil

## ABSTRACT

**Introduction:** In Brazil, the right to health has a constitutional and universal provision. However, the judicial route has been widely used to access health goods and services. **Objective:** To analyze the lawsuits of medicines filed by citizens of a Brazilian municipality. **Methods:** Quantitative and retrospective study evaluating 652 lawsuits filed in 2016 conducted in Uruguaiiana, state of Rio Grande do Sul. The information was made available by the State Department of Health. **Results:** 55.5% of lawsuits filed were related to drugs provided by the public health system *Sistema Único de Saúde* (SUS). 44.5% did not fit into the guidelines of the Brazilian Policy for Pharmaceutical Services. Most of the lawsuits were filed by women over 60 years old. Regarding the therapeutic classification, the most requested drugs were for the nervous system. The most described pathological condition according to the ICD-10 (International Classification of Diseases) was Diabetes Mellitus. **Conclusion:** These data corroborate the situation found in other parts of the country, demonstrating the need to reorganize the Pharmaceutical Service Policy to ensure universal and equitable access to medicines, as described in the Federal Constitution.

**Keywords:** Pharmaceutical services; comprehensive health care; judicial decisions.

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Corresponding author: Sandra Elisa Haas - Universidade Federal do Pampa - BR 472 KM 592 - CEP: 97500-970 - Uruguaiiana (RS), Brazil – E-mail: sandrahaas@unipampa.edu.br

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## INTRODUCTION

The Brazilian Federal Constitution of 1988 describe in its Article 6 the assurance of social rights for the Brazilian citizen as the guarantee of health care<sup>1</sup>. This right has its structure and organization defined in articles 196 to 200 of the Constitution. Integral Health care is a right of all and a duty of the state, which must generate social and economic policies to ensure universal and equal access<sup>1</sup>. The right to Pharmaceutical Services (PS) is part of this context and should also be understood as such, since it is part of comprehensive health care as described in the Organic Health Law<sup>2</sup>.

PS Policy involves a set of actions aimed at health promotion, protection and recovery for individuals and the public at large by considering drugs an essential ingredient and fostering their access and rational use<sup>3-5</sup>. Among the approaches to promote rational use and to enable the population to have access to these medicines is the use of the National List of Essential Medicines (NLEM). This instrument establishes the directory of drugs and pharmaceutical supplies within the scope of the Brazilian public health system *Sistema Único de Saúde* (SUS), elaborated to meet the fundamental principles

of universality, equity and integrality. This relationship is based on evaluations that consider the information of efficacy, effectiveness, safety, cost, among other aspects, obtained from the best scientific evidence available. There is still the State List of Essential Medicines (SLEM), the Special Component (list of medicines dispensed under special responsibility of the State of Rio Grande do Sul) and the Municipal List of Essential Medicines (MLEM)<sup>3</sup>.

Despite constitutional support, financial, administrative and managerial factors it is difficult to access to PS being fully met. Therefore the judicial route is widely used to achieve adequate treatment<sup>4,5</sup>. The lawsuits for requesting medicines that are already on public lists (such as SLEM) are legitimate. There is a consensus that this is an exercise of the right to individual therapy assistance<sup>6</sup> practiced by the Brazilian citizen.

As other public policies, PS faces major difficulties that prevent the full implementation of its actions. Among them, extreme bureaucracy and discontinuity in the supply of inventory<sup>7,8</sup> can be cited. Therefore, the right to health care combined with the difficulty in access to medicines became the judicial path as an alternative to guarantee access to medicines and treatments by citizens, a phenomenon that is called Health Judicialization<sup>7,9</sup>.

Brazil had its first lawsuits in the early 1990s and they were essentially demands of patients with AIDS. Currently, the actions are quite diverse and for numerous pathologies<sup>10</sup>. In the context of lawsuits in the SUS, this is a space in which two logics collide: the jurist, which defends the guarantee of rights, and the economist, which seeks the macroeconomic balance. The Judiciary follows the first line, while the executive power approaches financial rationality<sup>11</sup>.

In the realization of the right to health, we have the decisive role of the legal and social institutions that work together and produce results of results in public health policies. Legal professionals are authorized to enforce the right to health, taking as an example the importance of medical and pharmaceutical knowledge in the composition of Technical Support Centers in the courts. In this sense, the recognition of the right to health has gone through medicalization, or what reveals a conflict of proximity between law and health in Brazil<sup>12</sup>.

The flexibilization of drug registration regulations has been an international trend and is a consequence of the pressure for innovation and financing, resulting in increased judicialization, exposing the public budget planning to risk. In 2016, the regular supply of medicines in the SUS, in the three levels of health care, consumed R\$ 13 billion (approximately US\$ 4.3 billions), while the judicial branch, R\$ 8 billion<sup>13</sup>.

Lawsuits interfere with the PS cycle at several points. In selection, disregarding the stage in which drugs should make the official lists, based on scientific evidence, efficacy, cost-effectiveness, safety and quality of the drug. The phase of acquisition, the judicialization makes it difficult to obey the national law of

public bidding, which may favor fraud and high-priced retail purchases<sup>6,14</sup>.

In the state of Rio Grande do Sul, the reality of legal proceedings does not differ as to the prevalence of processes that request medicines already made available by the SUS<sup>15</sup>. In this state, since 2003, there has been a significant jump in the entry of new lawsuits, increasing significantly in the following years, having its peak in the years 2013 and 2014. Currently, the state still has a high rate of judicial health demands. The volume of monthly visits is significant, reaching more than 290,000 patients in administrative visits. In this context, it is important to highlight that, unlike most Brazilian states, Rio Grande do Sul has a municipalized system for delivering and ordering medications, which generates differentiated service, being able to receive drugs in the vicinity of his residence. Linked to this, such processes directly affect public coffers, where only in 2016 were spent R\$ 275,807,868.21 with judicial health demands<sup>16</sup>.

These processes directly affect public coffers. Expenditures on drugs provided by SUS through lawsuits has grown in recent years<sup>6</sup>.

These processes directly affect public coffers. Expenditures on drugs provided by SUS through lawsuits grew by more than 1,000% in seven years, reaching R\$ 1.1 billion in 2015<sup>17</sup>. Rio Grande do Sul stands out because it is the state that has the largest expenditure on the judicialization of health in the country<sup>18</sup> where medicines correspond, on average, to 70% of the health judicial actions attended by State Public Advocacy<sup>19</sup>.

This study was developed in the city of Uruguaiana with about 136,000 inhabitants considered the most populous city of west border of the RS. It was sought to evaluate judicial demand for drugs ordered in 2016 and to analyze the lawsuits as to clinical and procedural aspects, generating subsidies to face and knowledge of the profile of the lawsuits granted and the pharmaceutical specialties involved in these actions. PS in the municipality has 24 Family Health Strategy units, a Central Pharmacy, a Strategic Medicines Pharmacy and a Pharmaceutical Supply Center (CAF). Regarding human resources, PS has seven pharmacists and 13 pharmacy assistants. The municipality has a Municipal Lists of Essential Medicines. PS programming, it has a computerized management system that transmits to the Ministry of Health database. The acquisition takes place through a consortium for the associated management of public services and through bidding in the Price Record modality. Storage takes place at CAF.

## METHODS

The project was approved by the Research Ethics Committee University Federal of Pampa (UNIPAMPA) under protocol number 1,880,371 and CAAE 62726716.6.0000.5323.

This was a cross-sectional, quantitative and retrospective study. The information was obtained through consultation of

the Medication Administration System, used by the State Health Department of Rio Grande do Sul, which contains the information on the documents sent to the Municipal Pharmacy of Uruguaiana to comply with actions generated by patients' requests for medicines. The keywords used in the search in this search were: 1) situation: deferred; 2) Preference Dispensation: Legal proceedings; 3) agency: Uruguaiana; 4) Routing Date: from the year 2016. Data was collected by trained staff using a pre-tested structured questionnaire.

The variables of interest were defined based on the "Manual - Indicators for evaluation and monitoring of drug lawsuits" organized by Pepe *et al.*<sup>6</sup>, after adaptation according to the data available in the Medication Administration System. The data were described according to: 1) Sociodemographic characteristics of the applicant for the action: sex and age; 2) Procedural characteristics: state court and defendant of the action; 3) Medical-sanitary characteristics of the judicial processes analyzed: predominant ICDs, classification according to ATCC (Anatomical and Therapeutic System of Chemistry) and prescription drugs by the generic name; 4) Political-administrative characteristics of the judicial processes analyzed: Proportion of drugs per block of PS financing; Proportion of lawsuits that require drugs that are outside the components of the PS financing block.

Data were smoothed with a Libre Office Calc®, which made possible the systematization, processing, statistical analysis, and tabulation.

## RESULTS

Altogether, 676 lawsuits registered in 2016, concerning 436 different patients, were analyzed. Of these processes, 24 were related to inputs: tapes for monitoring capillary glucose, food supplements and special diets, leaving 652 actions related to the supply of medicines.

The lawsuits were filed against the Rio Grande do Sul State Health Department and were essentially filed in the civil court, which constitutes the jurisdiction responsible for judging civil lawsuits. Of the 436 applicants over 54% were female and over 60 years of age.

Based on the description of the International Classification of Diseases – 10<sup>th</sup> edition (ICD-10) indicated in the action, 177 ICDs were recorded along the processes, grouped into 57 different descriptions, of which six corresponded to 41.26% of the process indications (Table 1). In relation to the ATCC, classification recommended by the World Health Organization (WHO), the drugs were grouped according to the first classification level, which refers to the system in which the drug, in the specified indication, will act to achieve its effect (Table 2).

Of the 224 different drugs requested there was a higher incidence of those listed in the Components, Basic and Specialized, 26.84% and 26.38%, respectively. Altogether 55.52% of the judicial

actions corresponded to drugs with funding provided by the SUS, according to the available lists these components (Tables 3 and 4).

In relation to actions that requested drugs listed in the Basic Component, of the 175 the most frequent requests were: carvedilol (6.29%), omeprazole (5.71%), levothyroxine sodium (5.14%), clonazepam (4.57%). As for the Specialized Component of the 172 judicial actions that included medications of this list, the combination of formoterol and budesonide (10%), clopidogrel (8.72%) and salmeterol associated with fluticasone (7.56%), were the ones that presented the highest incidence in the processes (Table 4). A single drug of the strategic component was present in the processes of the year 2016, Bupropion, which consisted of 4 processes. Drugs listed in the special component were present in 11 judicial actions, of which 36.36% corresponded to sertraline, 27.27% methylphenidate and 27.27% to insulin aspart. Of the 290 judicial actions (44.48%) which requested drugs that do not have funding provided by SUS in the three spheres of government (city, state and federal government), insulin glargine (8.62%), rivaroxaban (5.52%) and tiotropium (4.48%) were the most requested by legal means in the year 2016 in the studied municipality.

**Table 1:** Profile of the prevalent pathological according to CID-10 grouping

Description	N	%
Diabetes Mellitus	76	11.66
Chronic diseases of the lower airways	58	8.90
Glaucoma	50	7.67
Ischemic heart disease	33	5.06
Systemic connective tissue diseases	27	4.14
Mood Disorders (affective)	25	3.83
Total	269	41.26

**Table 2:** Results of Lawsuits according to the first ATCC classification level

1st ATCC Level - Anatomical Groups	N	%
Nervous system	165	25.31
Digestive system and metabolism	103	15.80
Cardiovascular system	89	13.65
Respiratory system	66	10.12
Blood and Hematopoietic Organ	56	8.59
Sensitive Organs	50	7.67
Others	123	18.87
Total	652	100.00

ATCC: Anatomical and Therapeutic System of Chemistry.

**Table 3:** Classification according to the Pharmaceutical Care Component to which the requested drug is listed

Component	N	%
Specialized	172	26.38
Strategic	4	0.61
Basic	175	26.84
Special (Rio Grande do Sul)	11	1.69
Unlisted	299	44.48
Total	652	100.00

## DISCUSSION

Of the 436 citizens who filed lawsuits, it was found that the majority were female (54.82%) corroborating with results found in Rio Grande do Sul (54%) and other studies<sup>16,20,21</sup>. In the Federal District, the incidence is even higher, corresponding to 70% of the judicial actions<sup>22</sup>. This data suggests by women's greater concern over health, which motivates them to seek the judiciary as a way of guaranteeing the supply of the medicine that has been prescribed to them<sup>22</sup>.

Regarding the age range of patients, prevalence in the range above 60 years was verified, with 54.1% of the judicial actions. This result is consistent with the findings in the municipality of Santa Rosa in the same state (Rio Grande do Sul)<sup>21</sup>. The greater demand of the elderly population is justified by the fact that the aging of the population results in diseases specific to this stage of life, especially the chronic ones that persist for more than six months and are not solved in a short time. The country is aging and one of the results of this new configuration of the population is the greater demand for health services, among them drug treatment, which demands continuous and increasing expenses<sup>23</sup>. Therefore, it is important to consider this fact for management planning, which should invest in health promotion and protection actions to provide a better quality of life for the elderly.

There were 177 different pathologies recorded, grouped into 57 descriptions of which only six totaled 41.26% of the indictments of the lawsuits (Table 1). The prevalence of pathologies found does not differ substantially from those observed in another study<sup>6</sup>

which refers to chronic diseases, typical of a society that experiences the aging of the population.

When grouped according to the first classification level of ATCC, it is possible to observe a higher prevalence in the request of drugs that act on the Nervous System (25.31%), followed by digestive tract and metabolism (15.80%), cardiovascular (13.65%) and respiratory system (10.12%). Unlike the state of Rio de Janeiro, where studies indicated that the most frequent anatomic groups were the cardiovascular system followed by the nervous system<sup>24,25</sup>. However, a bibliographic review when analyzing 14 publications on the subject presented similar results to those found in this study when grouping the drugs according to the first level of the ATCC<sup>26</sup>. The data of these classifications, ICD and ATCC, are consistent with each other, indicating a higher incidence of chronic diseases, natural to aging, as well as a higher incidence of patients older than 60 who sought the courts to ensure their right to medical treatment.

Of the 224 medicines required, 55.52% are medicines that are part of the public lists, that is, they are standardized drugs. As well as other results described in the literature, such as the findings in the Catanheide *et al.*<sup>27</sup> systemic review, they were consistent with those found in the present study<sup>28</sup>. These data highlight the importance of rethinking the management of PS because, despite high drug costs, most lawsuits refer to drugs present on the lists.

It can be observed among the findings of the research that more than 50% of the judicial requests corresponded to drugs listed in the basic, specialized and special components list. The large number of medicines requested by court that are part of NLEM indicate deficiencies in the cycle of PS as regards to planning, management and patient care, problems in the supply of essential medicines to the population, being due to the lack of disclosure of the relationships (NLEM, SLEM and MLEM), the lack of adequate planning of the medicines available and the epidemiological profile of the municipality and state, failures in the acquisition of medicines due to budget planning reasons and/or lack of adequate planning and the insecurity of users due to the discontinuity of the supply<sup>29</sup>. In addition, part of the 26.38% of the legal proceedings included in the Specialized Component are due to the fact that access to them requires compliance with the inclusion criteria established by the Clinical Protocols and Therapeutic Guidelines of the Ministry of Health. The request of medication by administrative means requires a series of documents, examinations, and reports and often even though the user obtains this documentation, these do not comply with the requirements advocated and due to this the auditors do not defer the administrative request, generating legal proceedings, as a result.

It is undeniable that PS goes through a process of recovery and that many achievements have been attained. However, the results demonstrate a deficiency in the planning of the different stages of the PS cycle. Failures are observed in all planning stages,

**Table 4:** Profile of medicines requested in lawsuits analyzed

Most requested drugs	N	%	Component
Insulin Glargine 100 IU/ml	25	3.83	N
Formoterol, Fumarate +Budesonide	18	2.76	S
Rivaroxaban	16	2.45	N
Clopidogrel	15	2.30	S
Salmeterol Xinafoate + Fluticasone	13	1.99	S
Tiotropium, Brom.	13	1.99	N
Cilostazol	12	1.84	N
Carvedilol	11	1.69	B
Omeprazole	10	1.53	B
Atorvastatin	9	1.38	S
Quetiapine	9	1.38	S
Levothyroxine Sodium	9	1.38	B
Timolol 0.5%	8	1.23	B
Clonazepam	8	1.23	B
Bimatoprost 0.3 mg/ml	8	1.23	S
Travoprost	8	1.23	S
Gliclazide	7	1.07	B
Olanzapine	7	1.07	S
Valproate Sodium/ Valproic acid	7	1.07	B

N: Not listed; S: Specialized; B: Basic

management and patient care<sup>9</sup> making it impossible the access to the drug in its integrality.

Judicial intervention may cooperate for access to the necessary medicines provided that the clinic is pharmacologically subsidized. However, the reception of lawsuits based only on prescription leads to problems in the management of the national health system, as it compromises the formulation and implementation of PS policies. These facts demonstrate the importance of technical support, such as the pharmaceutical professional and other professionals, both in the management of medicines in public health and in the judicialization of access to medicines, since the processes are often evaluated only on the basis of compliance with the requirements present in the prescriptions, but this “method” does not take into account the fact that the drug is already being made available through the PS programs or that there is a therapeutic alternative present in the component lists.

The present study allowed a better understanding of this complex context that involves access to medicines through legal processes. At Uruguaiiana, judicial actions for the supply of drugs, in the majority, require those already listed in some of the components of the PS, that is, suggest the guidelines of the National Policy of Medicines are not being taken into account.

The data of this work corroborate with the information that appears in the literature in relation to the reality found in the

country, this demonstrates the importance of the technical support of professionals of the area, as for example, the pharmacist in the Judiciary when dealing with actions involving medicines and inputs<sup>7,30,31</sup>. In addition, it is of great importance to map out the judicialization of access to medicines in the country, since it is necessary to reorganize the PS to ensure the availability and supply of the medicines foreseen in the policies so that the judicial route is a means of access only for drugs that are not in the PS or that do not have therapeutic alternatives already available.

The data found in this article corroborate the situation found in other parts of the country, demonstrating the need to reorganize health policies to guarantee universal and equitable access to medicines, as described in the Federal Constitution. Thus, a better organization of pharmaceutical assistance, more simplified access to available services, periodic reviews of selected medicines and awareness of prescribers and members of the Judiciary about their importance in the rational use of medicines and better allocation of available resources, can contribute to reducing the judicial demand without compromising the constitutional right to health.

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