Legal proceedings to obtain medicines in Ribeirão Preto

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Abstract

This study aims to characterize lawsuits pleading for medicines in Ribeirão Preto, São Paulo, Brazil. A descriptive and cross-sectional study was carried out, which included all such judicial processes in the municipality between January 1999 and June 2014. Most of the time, public agents were responsible for legal representation (81.8% of cases), most of the prescriptions came from the private system (50.10%), and only 3% of prescribers concentrated nearly 30% of the cases. Diabetes and attention deficit hyperactivity disorder were the most prevalent diseases; with analogous insulins and methylphenidate being the most required drugs. It is concluded that, on average, 30% of the city's budget for the purchase of medicines is spent on medicines obtained through the courts.
Keywords: Health's judicialization. Health policy. Pharmaceutical services.

Resumo

Processos judiciais para obter medicamentos em Ribeirão Preto

O objetivo do trabalho é caracterizar ações judiciais pleiteando medicamentos em Ribeirão Preto/SP. Para isso, foi realizado estudo descritivo e transversal, que incluiu todos os processos desse tipo no município entre janeiro de 1999 e junho de 2014. Na maioria das vezes, agentes públicos foram responsáveis pela representação legal (81,8% dos casos), a maior parte das prescrições veio do sistema privado (50,10%) e apenas 3% dos prescritores concentraram quase 30% dos processos. As doenças prevalentes foram diabetes e transtorno do déficit de atenção com hiperatividade; insulinas análogas e o metilfenidato foram os fármacos mais requeridos. Conclui-se que, em média, 30% do orçamento da cidade destinado à compra de remédios é gasto com medicamentos obtidos por via judicial.
Palavras-chave: Judicialização da saúde. Política de saúde. Assistência farmacêutica.

Resumen

Procesos judiciales para obtener medicamentos en Ribeirão Preto

El objetivo de este trabajo es caracterizar las demandas judiciales para reclamar medicamentos en Ribeirão Preto, São Paulo, Brasil. Para ello, se realizó un estudio descriptivo y transversal, que incluyó todos los procesos de este tipo en el municipio entre enero de 1999 y junio del 2014. En la mayoría de las veces, agentes públicos fueron responsables de la representación legal (el 81,8% de los casos), la mayor parte de las prescripciones se originó del sistema privado (50,10%), y solo el 3% de los prescriptores concentraban casi el 30% de los procesos. Las enfermedades prevalentes fueron la diabetes y el trastorno de déficit de atención con hiperactividad; y los fármacos más requeridos fueron las insulinas análogas y el metilfenidato. Se concluye que, alrededor del 30% del presupuesto de la ciudad destinado a la compra de fármacos se gasta con medicamentos obtenidos por vía judicial.
Palabras clave: Judicialización de la salud. Política de salud. Servicios farmacéuticos.

Research

Approval CEP-FCFRP/USP 2.598.720

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The authors declare no conflict of interest.

When defining that the State must guarantee the "right to health", the Constitution provides citizens with instruments to claim access to necessary treatments or supplies, a process related to society's participation in the management of the Unified Health System (SUS)[1]. However, this claim can lead to the judicialization of health care[2] when it gives prominence to the Judiciary, making it an integral part of the therapeutic itinerary.

This judicialization is highly criticized, as it compromises the planning of medicines acquisition – the obligation to comply with the lawsuit determinations in the short term ends up demanding a parallel structure of purchases, which may take place via retail, for example. This has negative consequences, such as increased spending and the need to move resources from other areas, facilitating corruption schemes[3].

The counterargument is based on the very understanding of the Brazilian Constitution, that is: while health is a social right, judicialization would confirm the state's duty to provide procedures and therapeutic goods to the population. In other words, judicial means would be the citizen's weapon to fight public management inefficiency, as the incorporation of health technologies is flawed, and pivotal treatments are unavailable[4].

Regardless of its positive and negative aspects, reality calls for attention and caution from the agents involved (the government, the judiciary, and the society). The implications of judicialization must be weighed to balance patients' rights and public management sustainability. Within states and municipalities, there is the need for further investigation into the phenomenon given its heterogeneity; in other words, depending on the location, the demands are diverse and, therefore, require different administrative strategies[5].

The large number of lawsuits requesting medicines is not ignored by municipal and state departments, as well as by the Ministry of Health. However, the number of studies and surveys on the subject is still scarce. Thus, the analysis of the lawsuits in more detail becomes relevant in the search for appropriate administrative behaviors by the three spheres of government, mainly the municipalities.

This work describes and characterizes the phenomenon of judicialization (more specifically the pleads for medicines) in Ribeirão Preto, São Paulo, Brazil, based on lawsuits filed between January 1999 and July 1, 2014. Among the "medicines", our option was the necessary inputs for insulin application.

Method

This is a descriptive study with a cross-sectional design that included all the legal proceedings whose required goods were medicines or supplies for insulin application (infusion pump, catheters, storage, sensors, glucometer strips, and disposable needles) filed against the city of Ribeirão Preto, between January 1999 and July 1, 2014 (date on which data collection started). The lawsuits accepted by the state of São Paulo so that the compliance with the action would not incur costs to the city hall – despite being jointly granted against the state and city – are not part of this analysis.

The data were organized in a Microsoft Office Excel 2007 spreadsheet with the following variables: process number, year in which it was filed, situation (active or inactive, that is, whether it was still in force at the time of data collection), existence or no request for injunction, forum responsible for the judgment, deadline for compliance with the action, fine amount in case of delay, approved and rejected drugs, data of the requesting users (age, sex, address, diagnosis, and legal representative), required medicines and availability in the Municipal List of Essential Medicines (Remume) or the Specialized Component of Pharmaceutical Assistance (Ceaf), and the medical specialty of the prescriber. The data was gathered in the judicial process department of the Ribeirão Preto pharmacy division, where the cases are stored.

The total amount spent annually by the city government to purchase medicines between 2003 and 2014 had also increased, as well as the amount spent only on medicines obtained by lawsuit in the same period, for comparison purposes. These figures were provided by the Municipal Health Department and corrected for 2014 with the cost adjustment formula according to inflation: cost×(1+rate for the year)×(1+rate for the following year), the rate of the year being the National Consumer Price Index (INPC). The variables were presented in absolute and percentage values – averages were calculated for the variables "drug acquisition term", "legal representative", and "forum".

Results

3,417 lawsuits were brought up having the municipal government as a defendant, with 1,861

meeting the inclusion criteria. All actions included had an injunction granted by the judge. Of the applicants, 50.3% were women, and 48.7% were men. In 1% of the cases, the lack of information made it impossible to identify the gender of the requester.

Of the cases included, 95% corresponded to the period from January 2004 to June 2014, and 70.3% were claimed in the Public Tax Court. A total of 39 magistrates judged these actions, giving the municipality a maximum period of up to 30 days to comply with the injunction in 99% of the cases; in 66% of cases, the maximum deadline was of 15 days. The legal defense of the lawsuits was split into: Public Prosecution (71.7%), Public Defenders (10.2%), private lawyers (16.4%), and college law firms (1.7%).

437 different diagnoses were found, 12 of them (2.75%) corresponding to more than 50% of court cases (Table 1). 708 different medications were requested to treat these diseases, in addition to insulin supplies (Table 2), 67.3% of which were intended for problems related to the digestive system and metabolism, nervous system, and cardiovascular system. Of the lawsuits still active at the time of data collection, 13% of the drugs were listed under Remume and Ceaf. Considering only inactive processes during the same period, that number rose to 35.1%.

Table 1. Diagnostics referred to in lawsuits

Diagnosis	Total	%
Attention deficit hyperactivity disorder (ADHD)	283	13.2
Type 1 diabetes	208	9.6
Systemic arterial hypertension	101	4.7
Undefined diabetes	90	4.2
Type 2 diabetes	87	4.1
Depression	56	2.6
Brain stroke	50	2.3
Alzheimer's disease	47	2.2
Epilepsy	43	2
Macular degeneration	38	1.9
Dyslipidemia	38	1.9
AIDS	27	1.3
Others	1,068	50
Total	**2,136***	**100**

** It is equivalent to the total number of lawsuits that contained data on patients' diagnosis.*

Table 2. Items requested in court proceedings

Items	Total lawsuits	%
Methylphenidate	302	9.9
Insulin glargine	213	7.0
Clopidogrel	102	3.4
Aspart insulin	102	3.4
Humalog insulin	67	2.3
Insulin detemir	49	1.7
Baclofen	44	1.4
Diosmin + hesperidin	43	1.3
Insulin supplies	39	1.2
Cilostazol	37	1.1
Memantine	27	0.9
Kaletra	23	0.8
Coenzyme Q10	21	0.7
Tamsulosin	21	0.7
Losartan	20	0.6
Ranitidine	20	0.6
Risperidone	20	0.6
Others	1,943	62.4
Total	**3,093***	**100.0**

** Equivalent to the total number of cases that contained data on the requested medication.*

In 50.1% of the cases, the prescriptions came from private health institutions, 24.5% from the public system, and 25.4% from university hospitals. The drugs were prescribed by 764 different physicians and, of these, 706 had their registration number with the Regional Council of Medicine (CRM) found by the researchers. Of the 706 professionals, 3% concentrated almost 30% of the total prescriptions. One physician was connected to 106 cases, and another, in second place, to 50. The main medical specialties found were neurology (25%), endocrinology and metabolism (21.5%), and cardiology (10.8%).

The highest absolute expenditure on drugs obtained through the courts was recorded in 2009. That year, these expenses also reached the highest percentage concerning the budget for the purchase of medicines by the municipality, considering the period studied (Table 3). Between 2008 and 2014, the average annual costs per judicial process were approximately 24 thousand reais.

http://dx.doi.org/10.1590/1983-80422020281379

Table 3. Total amount spent on drug purchases and amount spent on drugs obtained through judicial means

Year	Total spent (R$)	Judicial means (R$)	%
2003	6,350,498.523	1,279,564.514	20.1
2004	6,832,744.492	1,340,759.586	19.6
2005	6,326,020.068	1,344,604.069	21.2
2006	5,937,232.579	1,350,895.891	22.8
2007	5,774,956.307	1,313,973.243	22.7
2008	11,421,686.73	2,366,519.856	20.7
2009	9,402,860.102	3,124,386.508	33.2
2010	10,214,943.11	2,154,407.646	21.1
2011	9,059,563.607	1,310,159.708	14.6
2012	10,199,875.43	1,441,110.698	14.1
2013	15,237,992.86	1,494,778.052	9.8
2014	8,666,911.587	1,405,278.427	16.2
Total	**105,425,285.40**	**19,926,438.20**	**18.9**

Source: data obtained from the Secretaria Municipal de Saúde de Ribeirão Preto

Discussion

This study has a large municipality as its object, according to the classification of the Brazilian Institute of Geography and Statistics (IBGE)[6]. Some data found here can be extrapolated to other cities of similar size, covering much of the country, since more than half of the Brazilian population lives in cities larger than 100 thousand inhabitants, of which 30.2% are in municipalities with more than 500 thousand inhabitants[6].

However, the possibility of generalizing the main characteristics of the judicialization of health care does not invalidate the need for studies by region, as populations have different demands and particularities. As for the sex of the plaintiffs, the focus of the study interferes with this variable, whether judicialization is assessed in general or concerning specific comorbidities with their epidemiology. Literature has not pointed out significant differences between men and women[2].

A sensitive aspect is medicine acquisition. According to information provided by the Municipal Health Department of Ribeirão Preto, the main form of purchase is electronic auctions, which last an average of 90 days from the drafting of the notice to the signing of the contract. This average period is three times longer than the 30 days provided in 99% of the analyzed cases, usually established by injunctions.

The impossibility of predicting values, associated with the requirement of speed to act, compromises all planning and, consequently, the health budget[7]. The granting of almost all injunctions has been common in courts[8-10], creating dangerous jurisprudence, in which the magistrate considers only the medical prescription to declare the urgency of the measure, disregarding any possibility of failure in the prescription or even external influence. When the merit of the action is finally judged, even if it is proved that a certain drug is not the most suitable treatment, the patient will have been using the drug for some time[11].

The commitment of public resources to meet these demands also exposes the Union. Data from the Advocacia-Geral da União show that, between 2008 and 2015, the resources used to supply medicines obtained in court increased more than ten times, from 103 million reais in 2008, or 1% of the total budget for medicines, to 1,1 billion reais in 2015, equivalent to 8% of the total budget for medicines[12]. In Ribeirão Preto, this percentage is even higher the average of the years studied is considered. In the period, purchases to comply with lawsuits corresponded to approximately 20% of spending on medicines, a rate that peaked in 2009, with a commitment of 33.2% of the total budget for medicines.

Varying percentages of the budget for the purchase of medication obtained through the

courts were found in the literature. In the state of Santa Catarina, Brazil, Pereira and collaborators [13] point to a percentage of 10%, while in the state of Paraná, Pereira and Pepe [14] found that these costs corresponded to twice the general expenses regarding medicines purchases. In any event, there is a substantial commitment of resources, destined to a restricted group of people to acquire drugs that are not always the most suitable for them. The situation is aggravated by the need to reallocate resources on the part of the State, which can be perceived as a privilege of the petitioner to the detriment of the population in general.

Another recurring debate about the judicialization of health care is that the judicial means would be used primarily by people from more privileged classes. It is understood that citizens who can afford to pay for their treatments should not have their drugs afforded by lawsuits. However, it is necessary to consider that the SUS is not restricted to the least favored; its principles converge to universal care to all Brazilian citizens, regardless of their financial situation [15].

Furthermore, this is an interpretation without a solid basis, mainly because the analysis usually highlights two specific variables – legal advice and the origin of the prescriptions –, which is not enough to affirm that judicialization is a class privilege. In most studies presented it was not possible to predict the applicant's social class with a good level of certainty. To analyze this issue, it would be necessary to know the income of all of them.

Every request for medication by lawsuit is based on diagnosed diseases. As demonstrated in Table 1, 12 diagnoses (2.75%) accumulate more than half of the cases. This type of information can be used in the analysis of strategies and actions related to the judicialization of health care.

Mainly on diagnoses, another relevant fact is that, among the prevalent illnesses, the treatment of attention deficit hyperactivity disorder (ADHD) is the only one not offered by the municipal management. Some professionals insist on prescribing different drugs, regardless of their knowledge of standardized therapeutic alternatives. In this study, only 3% of prescribers are linked to almost 30% of the actions, and a single physician concentrates a third of the cases. Therefore, few professionals have a great impact on the municipality.

According to Campos Neto and collaborators [16], a single physician was the prescriber in 43% of the lawsuits requesting adalimumab – a medicine for rheumatoid arthritis. The main hypothesis to explain the fact would be the influence of the pharmaceutical industry. In another study [17], physicians reported incentives on the part of companies to encourage the prescription of medications. Practices included harassment of medical students, support for community experiences to access insulin pumps, and a load of advertising reaching out for the population.

With the data presented, it is not possible to prove the relationship of physicians with the pharmaceutical industry; however, many studies suggest this association, which requires careful evaluation. Understanding the reason why the same physician has so many judicialized prescriptions can help to develop strategies to reduce the number of cases. The professional himself is often manipulated since the companies' harassment does not happen explicitly. As an example, information can be distorted to induce the prescriber to choose a specific treatment [16,17].

As in other studies, analogue insulins of the type glargine, aspart, lispro, and detemir are also among the most requested drugs. However, the efficiency of this medication is not guaranteed if compared to available alternatives. In 2014, through the National Commission for the Incorporation of Technologies in SUS (Conitec), the Ministry of Health launched two reports on the use of insulin analogues for type 1 and 2 diabetes. Based on specialized literature, the documents concluded that there is no evidence that these insulins provide significant improvements in glycemic control when compared to those already available in SUS. Their incorporation, therefore, was initially discouraged [18,19].

In 2018, Conitec revised the decision, opting to incorporate ultra-fast insulins for patients diagnosed with type 1 diabetes mellitus who were unable to control the disease with first-line insulins provided by SUS (regular and NPH). In addition to the scientific evidence, the opinion was probably revised due to the volume of lawsuits requesting ultra-fast versions in the country.

Considering only the processes active at the time of collection, 13% of the requested drugs were listed under Remume and Ceaf – a reduced percentage when compared to other studies, with numbers that go up to 52% [20]. At least in part, the data can be explained by the type of request of the case, as it is common that the lawyer includes all medications necessary for the patient in the request, and not only the object of the demand.

Thus, when fully granting the action, the magistrate also judicializes the supply already guaranteed by the network.

There is consensus on the management difficulties caused by the judicialization of health care and the need to solve this problem[1,7,14]. However, since it is not possible to simply end the lawsuits, the question is to better manage the situation. The first step is to deconstruct the idea of judicialization as a purely legal phenomenon. Trying only to defend oneself in the courts has proven counterproductive since most actions are not upheld, even if the argument is only the medical prescription.

The phenomenon of judicialization is complex, with an administrative character that permeates several measures and policies. This is precisely where the discussion should begin. It is easier to solve the problem through management, where more control can be exercised than within the legal environment.

Silva and Shuman[1] propose this path through a strategy of dialogue and proximity between actors (managers, physicians, pharmacists, patients, magistrates, lawyers). It would be a matter of working out agreements – before filing the lawsuit, the Public Ministry seeks the Municipal Health Department to justify the refusal of supply and present alternatives. The secretariat then seeks out the team of prescribers to reach consensus on possible updates to the list of drugs supplied; and the magistrates, instead of simply accepting the injunction requests, undertake to analyze the opinion of a specialized technical team.

The study by Silva and Shuman[1] points out elements to be worked on, weaknesses, and areas where the dialogue seems to fail – for example when physicians prescribe drugs that are not on the lists, even when there are therapeutic alternatives; or when magistrates grant preliminary injunctions with shorter deadlines than the time required for their acquisition, without understanding the administrative problem that this generates. Improving communication would help contain the judicialization of health care, which would continue to exist, but with a manageable impact.

The main limitation of studies on this topic, as emphasized by systematic review by Gomes and Amador[11], has been the small number of cases analyzed. Considering articles that had data collection as a method, the authors concluded that 47% of the studies had sampled less than 500 cases, and 70% included less than 1,500. Among the works listing more than 2,000 processes, none had municipal coverage. However, the present study found 3,417 processes, of which 1,861 were analyzed. The robustness of the data allowed a general diagnosis of the judicialization of health care in the municipality of Ribeirão Preto, pointing out areas in which the public administration must develop strategies and intervene.

Final considerations

The present study describes the phenomenon of the judicialization of health care to obtain medicines in Ribeirão Preto, a municipality that responds to many lawsuits regardless of its wide list of standardized drugs. The results show that most lawsuits are limited to a few prescribers, which confirms the importance of dialogue, the development of agreements, and the search to understand the choice for certain treatments. The lack of communication becomes even more evident when another result of the study is taken into consideration: there are therapeutic alternatives for the treatment of several of the diseases that are listed as the reason for these lawsuits.

The data presented can help municipal management to formulate actions to reduce the number of lawsuits aimed at acquiring medicines. The study does not end discussions on the subject but, together with other studies, it could help to characterize the judicialization of health care in the country, a phenomenon that opposes the individual to the community.

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Participation of the authors

Lauro César da Silva Maduro designed the study and participated in all of its stages. Leonardo Régis Leira Pereira advised the research project, contributing to design the project and review the article.

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Received: 10.15.2018
Revised: 3.14.2019
Approved: 5.17.2019

Research